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FOR RELEASE

March 2, 2023 | News

PFD Management Opportunity Fund 3001, LLC Announces:

Announced today by Robert Pryke PFD Capital Partners, LLC, Director and Fund manager for PFD Management Opportunity Fund 3001, LLC, additional points of interest related to its RAD/ iKnee portfolio project.

UPDATE ON THE iKNEE COMFORT STUDY AND THE PATH FORWARD

PFD/iOrthopedics, Inc. (**PFD/iOI**) has announced further details on its upcoming **iKnee Comfort Study**. As was released previously, **PFD/iOI** has been granted authorization to conduct up to a 10,000-patient **Comfort Study** to gather the longitudinal data required to move the **iKnee** application of the **RAD** technology to FDA approval and commercialization. The study has been authorized by the FDA under its Investigational Device Exemption (IDE) which permits a clinical trial to gather data on the technology's efficacy and safety based on its qualification of being a Non-Significant Risk (NSR) device. The First-In-Human (FIH) implant of the **iKnee** will be conducted at the Memorial Care Surgical Center in Long Beach, CA. later this year. Eric Hansen, who is **PFD's** Director, Co-Founder, and Clinical/Asc Operations Manager, has been selected as Patient One in the study's cohort group. Eric has suffered from debilitating knee pain for more than seven years due to injuries sustained from both sports and heavy use issues and is currently at the point where a Total Knee Arthroplasty (TKA) would be the traditional next step. As such Eric meets all the criteria established in the **Comfort Study's** protocols as a candidate for the iKnee implant. The surgery will be performed by **PFD/iOI's** Chief Investigator, Dr. Christopher Woodson, who is a board-certified orthopedic surgeon and sports medicine physician,

Eric Hansen
PFD's Director, Co-Founder & FIH Candidate

Memorial Care Outpatient
Surgical Center

Dr. Christopher Woodson
Principle Investigator & FIH Surgeon

and founder of Beach Orthopedic Specialty Institute. Dr. Woodson will also be serving as the Principle Investigator for the **Comfort Study's** ongoing trials.

Comfort Study Purpose

The **PFD/iOI Comfort Study** is designed to allow the company to gather critical data in three major areas:

1. The ability of the patient to tolerate the **iKnee** implant both from a bio-compatibility standpoint and an ortho-comfort level.
2. The ability of the **iKnee** implant to decrease or eliminate the patient's pain level as it applies to the use of the impacted joint.
3. The ability of the **iKnee** to maintain or expand the patient's quality of life as it pertains to daily activity, leisure and recreational movement, and/or active sports engagement.

Candidate Selection

Candidate selection for the study will be done by **PFD/iOI's** Institutional Review Board (IRB) which is being sponsored and managed by Advarra, who is a global leader in supplying IRB, institutional bio-safety committee, and research compliance services to clinical trial sponsors, CROs, hospital systems, academic medical centers, and investigators. Candidates for the trial must meet the following criteria:

- Male or female above the age of 50.
- Have a BMI of 30 or less.
- Have had a continual and chronic issue with their knee joint.
- Have a pre-operative Visual Analogue Pain Scale (VAS) score of ≥4.
- Have failed all standard therapeutic care and treatment and are now candidates for a TKA.
- Be referred to the program by their Primary Care Physician (PCP) or by a qualified referring orthopedic specialist.
- Have no disqualifying health conditions or risks.

Once prospective candidates have submitted their applications, they are vetted by the **PFD/iOI** IRB for possible inclusion into the study. The application screening process consists of a series of steps to ensure that the candidate will be a viable cohort for the program and that there is an anticipated benefit to the patient's knee issue and quality of life as a result of participation. The application review consists of an initial

CANDIDATE APPLICATION PROCESS

Candidates for the PFD/iOI Comfort Study are first evaluated by a PFD/iOI certified physician.

If determined to be a viable candidate, the PFD/iOI IRB begins the process of gathering all the relevant patient records including their latest radio imaging files which are used to construct the iKnee implant.

Once all records are in pace, the candidate's application packet is reviewed by the PFD/iOI IRB to make a determination on acceptance into the study.

If approved, the candidate is brought in for a final review of the study and an Informed Consent package is agreed to after which the patient is put on the surgical schedule.

patient consult with a **PFD/iOI**-certified physician to include:

1. Initial patient background review.
2. Physical examination including a VAS and joint mobility assessment.
3. Initial consult on study overview, implantation procedure, and benefit/risk assessment.

Based on this evaluation, a request for medical records, copies of the latest radiological films, which can include X-rays, CAT and MRI scans, and any needed lab work is made. Once procured, an in-depth review of the applicant's records, films, and labs is made by the qualified **PFD/iOI** surgeon along with the IRB. If at this point the applicant is deemed to be a viable cohort, a second consult is scheduled during which the study protocols and the implant procedure are once again thoroughly reviewed. If the applicant decides to move forward, a detailed Informed Consent document is signed along with any related additional release and medical information paperwork. Once processed the patient is given a case ID and a surgery date is scheduled.

iKnee Implant Procedure

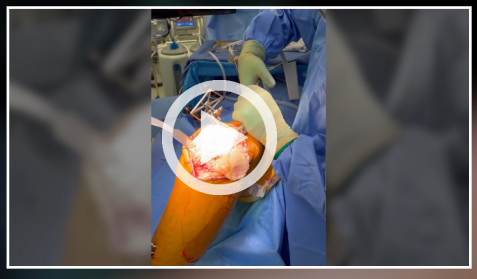
At this point, the patient's latest CAT scan is digitized and brought into **PFD/iOI's** 3D imaging platform utilizing the Materialise Mimics Suite to construct an STL file of the patient's distal femur. Based on this model, the patient's **iKnee** is modeled for printing. The custom-tailored **iKnee** is created by the **PFD/iOI** Arburg Freeformer 300-3X printer using Quadrathane™ ARC, a polycarbonate-based thermoplastic polyurethane that offers superior bio-compatibility, superior chemical resistance, and oxidative stability for use in long-term body implantable applications. Quadrathane™ ARC is a USP Class VI

FINDING AN ALTERNATIVE TO TKA

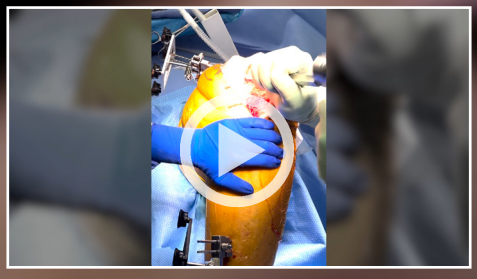
PFD/iOI was created to develop viable options for patients facing invasive major orthopedic surgery treatments as their only option for relief. Total Knee Arthroplasty, or TKA, is one of the most invasive and disruptive options for patients with chronic knee joint issues. TKA's require the removal of significant portions of the patient's distal femur and tibia, as well as damage to ligaments, tendons, and surrounding cartilage in order to make room for a prosthetic device. The cost is enormous and the chances of rejection, side effects, no increase in mobility, and even death are potential risks. With the **iKnee**, **PFD/iOI** hopes to provide at least a temporary and effective alternative to TKA. The **iKnee** is an outpatient, arthroscopically-based surgery that requires no removal of bone or tissue and has the promise of not only providing immediate pain relief; but partial if not the complete restoration of knee function.

Watch the videos below which demonstrate both the invasive nature of traditional surgery as well as the process for implanting the **iKnee** device.

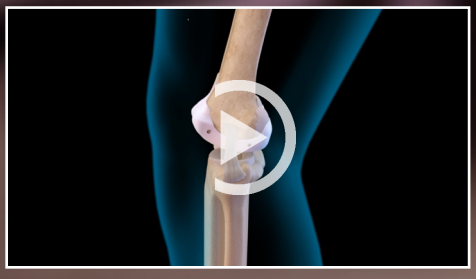
Dr. Woodson demonstrates the removal of osteophytes during a TKA



Dr. Woodson shows how ligaments are revealed during a TKA



This video provides an overview of the candidate application process and the iKnee procedure.



and ISO-10993 compliant hemocompatible material that is used across a wide range of medical applications and is felt to be the perfect material to provide the protective cushioning for the iKnee expectations.

After printing the patient's **iKnee**, the piece is sent for AMT PostPro processing. At this stage, the implant is vapor smoothed to refine the surface and seal it for easier cleaning and sterilization. Turnaround time from film digitization to implant in hand takes only a few days.

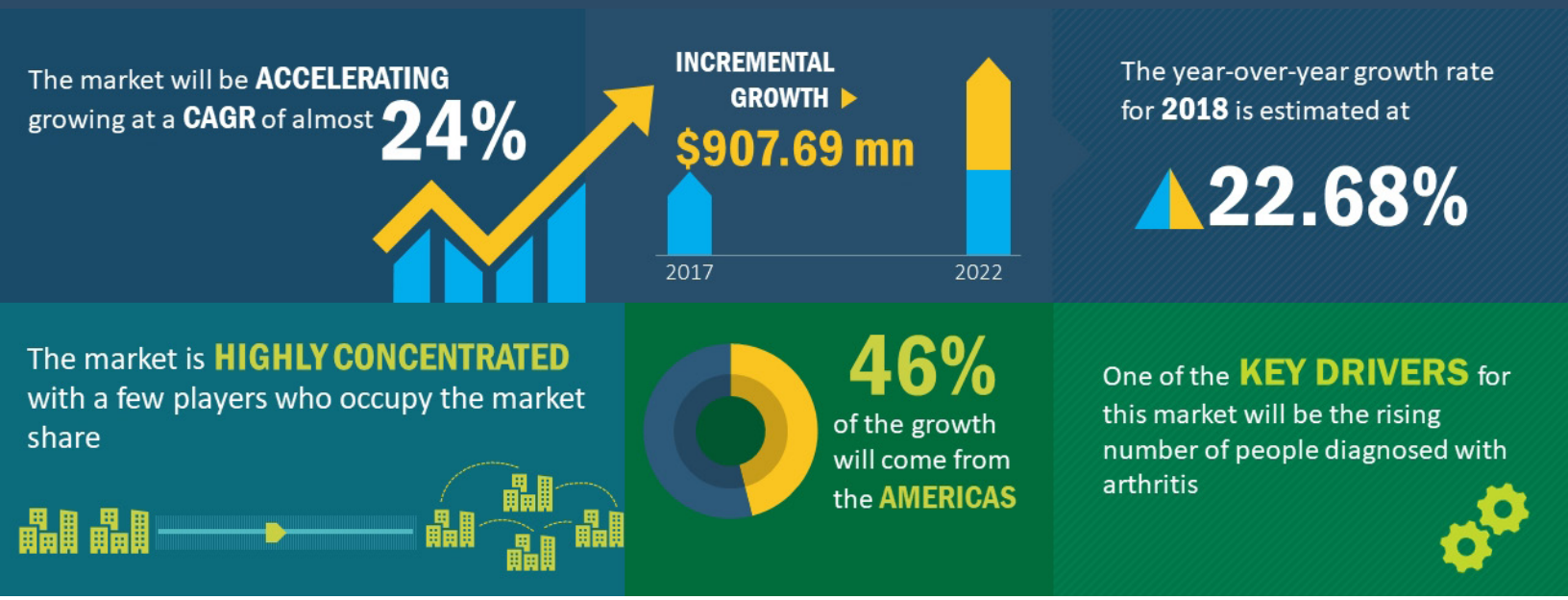
One week prior to their scheduled surgery, the patient is again evaluated for the most current VAS assessment, mobility range, and review of any significant changes that may have occurred.

The procedure itself is done on an outpatient basis at a qualified **PFD/iOI**-authorized surgery center. The surgery takes an hour to perform and barring any complications, the patient is released and able to bear weight on the implanted knee that day. On the day of surgery, the patient is admitted and prepped. They are then given a general anesthetic and once stabilized, the knee is prepared for an arthroscopically facilitated debridement. A small incision is made, and an osteotome is used to remove any osteophytes, loose materials, or bony protrusions on the femur, the tibia, and the patella. There is no disturbance of any of the patient's ligaments or tendons, and the remaining healthy cartilage is preserved. Once the joint is prepared, the **iKnee**, which has been compressed and rolled to a fraction of its size, is inserted into the spacer. The **iKnee** is then opened up and maneuvered into its correct position by the surgeon. Because of the elasticity of the **iKnee** polymer material, the implant creates a virtual hand-in-glove fit to the distal femur. Sutures and biodegradable screws are then used to secure the **iKnee** to the femur. Once the **iKnee** is in place, a range of motion test is performed on the joint, and any adjustments are done to provide the best positioning for maximum flexibility and comfort.

the iKNEE Benefits

The **iKnee** Implant provides many benefits when considered against the cost in time, money, and risk of a Total Knee Arthroplasty.

1. Total cost of multi-day surgery and recovery as compared to a 3-hour outpatient procedure.
2. Immediately weight bearing and able to enter PT and OT in order to get back to life within weeks, not months or years.
3. Almost zero risk of infection or rejection compared to TKA.
4. Preservation of bone, cartilage and ligaments as opposed to a radical removal of tissues with TKA
5. Higher potential for full knee mobility and quality of life as opposed to restrictions caused by a prosthetic device.

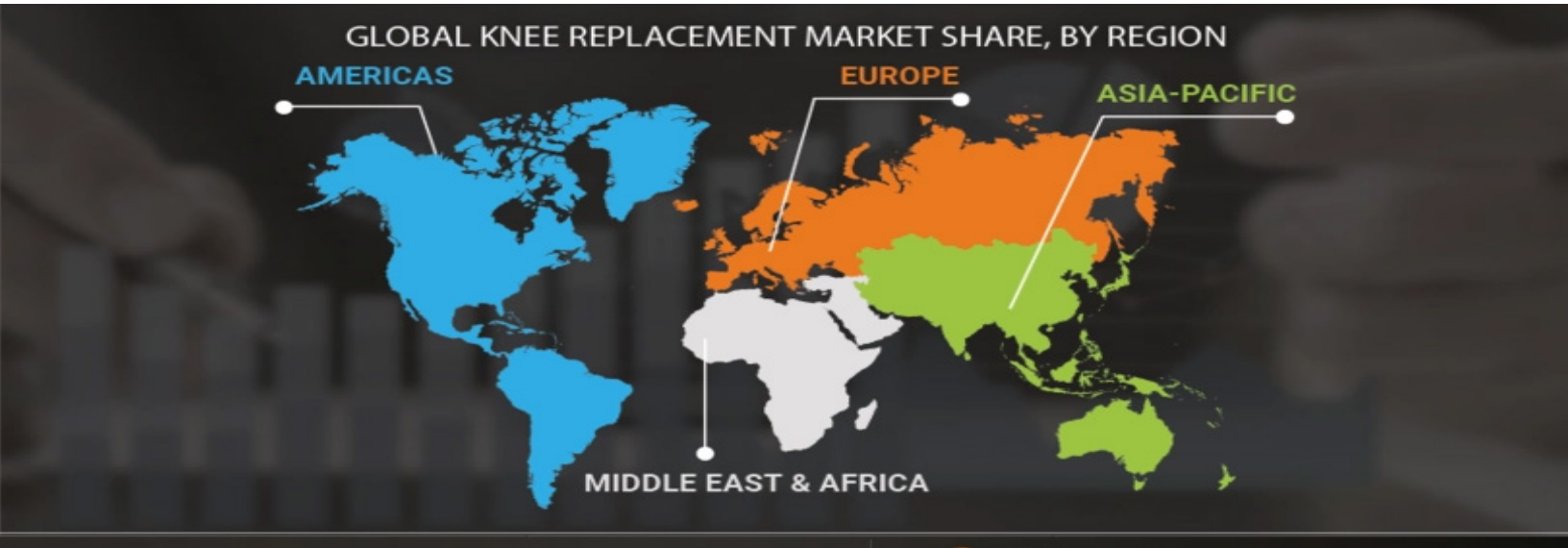


The patient's incision is then closed, and they are moved to post-op to recover from the anesthesia.

Once awake, a post-operative evaluation is made on the patient. Since the **iKnee** enables immediate weight-bearing, once cleared the patient is released to return home. The patient will have some limited post-op restrictions on use, but full recovery time is days rather than weeks or months as they would have had with a TKA.

Patient follow-up for the study is performed at 10 days, week six, week 12, and week 24 in order to assess the patient's reaction to the **iKnee**. In these post-operative follow-ups, the patient is assessed for:

1. Comfort and level of pain
2. Joint mobility
3. Infection or inflammation
4. Evaluation of post-op imaging
5. Quality of life changes.



on creating a new paradigm

"As a surgeon, researcher, and educator since 1981, I've embraced orthopedic evolution. Standards and regulation permitted little change in total joint replacements (TJRs). Advanced arthritis currently leads to joint resection, then implantation of metal components, sacrificing cartilage and ligaments. There remains a gap between pills and protheses, for severely debilitated knee patients. My work from 1980, in 10,000 surgeries, treating 25,000 patients, for 100,000 injuries, preferred salvage. Twenty-first century materials, design and technology now enable RADs (Resilient Arthroplasty Devices); iKnees resurface knees to pad and restore joints.

RADs "do no harm", offering reasonable expectations of temporary comfort, to delay or avoid total knee replacements. iKnees create faster, cheaper, better customized options to reduce pain, and improve function. IRB approved IDE allowances, with non-significant risk (NSR), anticipate launch in 10,000 patients soon. iKnee simplicity intends outpatient joint preservation with speedy return to sports, work, and a better quality of life."

Dr. R. Thomas Grotz – Inventor of the Technology

Comfort Study Post-Operative Follow-Up

The data is carefully recorded at each step and becomes part of the ongoing evaluation to ascertain several criteria including:

1. **iKnee** design for possible improvements.
2. Material integrity and bio-compatibility.
3. the ability of the implant to lower or eliminate joint pain.

Though the study is focused on the **iKnee's** ability to provide comfort and relief for a minimum six-month period, **PFD/iOI** will continue to perform multi-year follow-ups with those cohorts who maintain their implants until such a time as they have a TKA procedure performed.

If, as expected, the initial FIH procedure is successful as defined by the study's criteria of comfort, reduced pain, and bio-acceptance, enrollment of the next group of cohorts will begin immediately and evaluation and approval of other surgical centers across the US will proceed.

PFD/iOI Revenue Streams and the TKA Marketplace

PFD/iOI has stated its intention to not only be the manufacturer of the **iKnee** implant, as well as subsequent **RAD** applications, but also the managing authority for the physicians and centers where the implants will be performed. As such, **PFD/iOI** not only anticipates having a significant revenue stream from the modeling and manufacture of each custom implant, but also from each of the billable aspects of the Rev Share program. Billable services can include but are not limited to:

- Initial and follow-up patient consults
- Diagnosis or treatment of intra-articular joint pathology
- Third-party consults (PCP, Ortho specialist, Therapy provider, etc)
- Radiology scans
- Surgery center cost
- Surgeon and support cost (Anesthesiologist, OR nurse and care staff, etc.)

- Materials used in surgery.
- Various surgical procedures performed during the implant including:
- Arthroscopy Knee Diagnostic
- Osteochondral Autograft Arthroscopy
- Arthroscopic Osteochondritis Dissecans Fragmentation Removal
- Arthroscopic Chondral Fragmentation Removal
- Arthroscopic Plica or Shelf Resection
- Arthroscopic Major Synovectomy
- Arthroscopic Knee Debridement
- Arthroscopic Knee Abrasion arthroplasty (including drilling or micro-fracture)
- Arthroscopic Knee Meniscectomy
- Post-op therapy

With the current US TKA market sitting at $9.8 billion and the global TKA market set to grow by more than $2,408.49 million by 2027 with a CAGR of 22.15% and with 39% of that market being in the US , **PFD/iOI** anticipates it can capture a significant percentage of this expanding sector.

About PFD/iOrthopedics. Inc.

The **PFD/iOrthopedics INC** (**PFD/iOI**), **Resilient Arthroplasty Device** (**RAD**), and its first product candidate the **iKnee**, is a patented implantable medical device by which patients presenting with osteoarthritis will find pain relief through the padding, cushioning, and protection of the damaged joint surfaces. The **RAD/iKnee** will change the pain profile by covering the dominant surface of the damaged joints very much like the original cartilage. The device has been IRB IDE authorized for human use in the first 10,000 qualified patients.

PFD/iOI is introducing this 21st Century, personalized, patient-driven, novel, and highly disruptive, restorative, joint salvage outpatient approach as an effective solution to fill the gaping, costly, inefficient, and non-therapeutic void between pills, shots, bracings, physical therapies, and the limiting of daily activity for patients suffering from osteoarthritis.

This additional interventional option may potentially eliminate or at least delay the much more dramatic, and life-altering surgical replacement of joints with a simple outpatient procedure.

The intent was that this principle would be used in all mammalian joints; think animal and human including the knee, hip, shoulder, etc throughout all the long bone interfaces (appendicular skeleton).

Strategic Alliances

The following is provided for purposes of giving the reader deeper appreciation of the strategic alliances involved with bringing the PFD/iOI technology to commercialization.

QUADRATHANE

Quadrathane™ ARC is a family of aromatic polycarbonate-based thermoplastic polyurethane. It offers superior bio-compatibility, superior chemical resistance, and oxidative stability for use in long-term body implantable applications. It is naturally clear, hemocompatible, and is USP Class VI and ISO-10993 compliant. Quadrathane™ ARC is used across a wide range of medical applications including chronic indwelling catheters, feeding catheters, pacemaker leads, coatings, orthopedics, and other applications where superior chemical resistance is required. The iKnee will use Quadrathane ARC 70 A.

MIMICS INNOVATION SUITE

In furtherance to complete comprehensive personalized medicine, PFD/iOI has utilized Materialise, as the industry-standard medical image-based engineering software and service, Their Mimics Innovation Suits (MIS) puts us in control with the most advanced tools to support our mission to improve patient care. Medical image data thus serves as a powerful basis for engineers and researchers striving for solutions that will lead to safer and more predictable personalized patient outcomes.

The MIS was designed to make using medical image data for engineering purposes as easy and rewarding as possible.

VAPOR SMOOTHING

Post-processing is required to finish 3D-printed parts for end use. Traditional methods are slow, difficult to predict consistency, and can account for up to 60% of the part cost.

PostPro, developed by AMT, is a digital post-production technology platform that automates the manual and costly steps associated with legacy 1.0 'low volume and prototyping' post-processing and enables functional 'high-volume end-use parts' production from 3D printers.

PostPro allows companies to leverage the benefits of additive manufacturing at scale, by providing an order-of-magnitude improvement in part throughput, performance, quality, cost, and safety.

The benefits of vapor smoothing to seal surfaces for easier cleaning and sterilization are game changers for the medical and food industries.

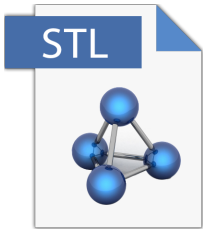
Vapor smoothing surfaces prevent liquid absorption, allowing for the development of new applications in numerous industries. Vapor smoothing the parts in preparation for surface coating and dying will significantly reduce the time needed to get perfect results.

Repeatability and consistency of performance results directly enable the scaling up of manufacturing processes and volumes.

ARBURG PLASTIC FREEFORMING

ARBURG Plastic Freeforming (APF) technology uses qualified standard granulates employed in injection molding technique. Using the material jetting method, these granulates are melted and discharged to fabricate thermoplastic parts. Freeformer 300-3X is an industrial 3D printer produced by ARBURG additive. ARBURGadditive is a 3D printer manufacturer based in Germany. The Arburg Freeformer 300-3X will be placed in our PFD/iOI RAD printing clean-room.

STL File



The STL file format is the most used file format for 3D printing. When used in conjunction with a 3D slicer, it allows a computer to communicate with the 3D printer hardware. The STL file format has been adopted and supported by many CAD software packages. Today it is widely used for rapid prototyping, 3D printing, and computer-aided manufacturing.

ENGINUITY WORKS

Enginuity Works provides our engineering consultation for the full range of product development services, Industrial Design, Mechanical Engineering, Electrical Engineering, Prototyping, R&D, and Manufacturing Management. Their approach identifies the best fit of our own expertise and capabilities with their engineering team.

ADVAARA

Under FDA regulations, an Institutional Review Board is group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the

research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

Regardless of a project's scope, therapeutic niche, or the number of investigators, Advarra is our partner in the conduct of efficient, responsible research. Objectivity and concern for participant well-being drive all review decisions.

FIRST IN HUMAN (FIH)

A type of clinical trial in which a new drug, procedure, or treatment is tested in humans for the First time. Also called First-in-human study.

The following section is provided as a very basic tutorial on regulatory path and some of the terms, processes, and programs that new medical technologies must navigate to become commercial in the United States.

NON-SIGNIFICANT RISK

The FDA does not regulate Non-Significant Risk (NSR) devices.

The Sponsor has the responsibility of making a Significant Risk (SR) or NSR determination and may utilize the services of an IRB, though this is not required.

The RAD/iKnee device does not refer to curing any disease. We are implanting this minimally invasive device for a patient's quality of life issues while they await a full TKA. This may be for comfort, mobility, or many other non-disease-related terms.

What is a Non-significant Risk Device Study?

NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b).

An IRB's NSR determination is important because the IRB serves as the FDA's surrogate for review, approval, and continuing review of the NSR device studies.

An NSR device study may start at the institution as soon as the IRB reviews and approves the study and without prior approval by FDA.

TITLE 21–FOOD AND DRUGS
CHAPTER I–FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H – MEDICAL DEVICES

PART 812 — INVESTIGATIONAL DEVICE EXEMPTIONS
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2

FDA Pathways

IKNEE COMFORT STUDY

Description: the iKnee seeks to provide temporary comfort and improved function for patients awaiting total knee replacement arthroplasty (TKA). Reasons to delay a TKA include but are not limited to the need for weight loss, wound infection healing, implant availability, and required medical or psychological patient preparations. iKnee use determinations are made between the patient and caretaker. The subject population is individuals with refractory disabling knee pain who failed other conservative measures and are on track for TKA. The iKnee is to provide comfort, it is not intended to treat a disease, or underlying cause leading to TKA.

Objective: To study iKnee efficacy on quality of life and activities of daily living in patients awaiting TKA. The data will be used to improve possible designs to enhance patient comfort.

Procedure: A rolled polymer is inserted through a small parapatellar incision and then expanded to fit and pad the distal femur, providing a stable cushion made of medical polymers used safely and reliably for decades. The procedure is expected to take about 30 minutes, and involves an incision of 2-3 cm of subcutaneous tissue into the joint capsule, and an incision less than one cm in depth. The iKnee device is then inserted into the knee capsule. No muscles, tendons, or ligaments are cut.

Study Rationale: Total Knee Arthroplasty (TKA) has become one of the leading operations for senior citizens, both in cost and frequency. When a patient has a disabling knee condition limiting mobility and quality of life there is only one medical option, TKA. The TKA operation is a significant procedure, involving the removal of the bottom of the femur, the top of the tibia, and part of the patella to make space for the artificial metal and polyethylene prosthesis.

The study is designed to increase the patient's quality of life, functionality, and comfort while they await the knee replacement operation (TKA). The iKnee procedure poses almost no medical risk to the patient, either as a procedure or as a risk to the patient's knee as the decision has already been made to remove the joint.

INVESTIGATIONAL DEVICE EXEMPTION (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study and;
- required records and reports.

FDA designation of the iKnee as an NSR Device. Pathways for commercialization are to be determined based on the commercialization path of the purchaser of IP.

Seven FDA Pathways to Bring a Medical Device to Market

1.) Premarket Notification 510(k)

The Premarket Notification 510(k) pathway is the most common route taken when launching a medical device. Almost all Class II devices and certain Class I devices will require a 510(k).

The purpose of a 510(k) submission is to provide the FDA with documented evidence showing that a medical device is substantially equivalent in terms of safety and effectiveness to a predicate device.

A predicate device is one that is already legally marketed and shares the same intended use and technological characteristics as the new device. The requirement is to compare the new device with the predicate by summarizing information from the design controls process, such as design features and verification testing.

The FDA typically processes 510(k) applications in 30-90 days. Depending on the robustness of the initial application, there may be a period of back-and-forth discussions, which can delay the process. It is important to plan and provide all appropriate documentation at the time of initial submission.

2.) Premarket Approval (PMA)

Class III devices, and any device that cannot provide substantial equivalence to a Class I or Class II device through the 510(k) process, must use the Premarket Approval (PMA) pathway.

The PMA process is the most involved as scientific evidence, typically in the form of a clinical trial, is needed to prove the safety and effectiveness of the new device. The FDA will either approve or reject the application within 180 days. The different steps of the review process include:

- FDA staff will determine completeness through an administrative and limited scientific review
- FDA staff will conduct an in-depth scientific, regulatory, and Quality System review
- An advisory committee will review and offer any recommendations.
- Any final deliberations will occur, and the FDA will document and notify the applicant of their final decision.

Although the premarket approval process sounds intimidating, it is the right option for a high-risk, Class III device.

3.) De Novo

If the applicant is developing a lower-risk, "novel" device and struggling to find a predicate, the De Novo pathway might be the best option.

The De Novo pathway has been around since 1997 but many people do not know about it

since it is not very commonly used. Companies that do not qualify for 510(k) clearance, since they cannot provide substantial equivalence to a device on the market, should learn more about the De Novo pathway.

Since comparison to a predicate is not needed, companies have a "blank canvas" when it comes to labeling and can set a standard that may give them a competitive advantage over others. One of the key things to remember about the De Novo pathway is that the device must present low to moderate risk through a robust risk mitigation strategy.

4.) Humanitarian Device Exemption (HDE)

The Humanitarian Device Exemption (HDE) pathway is for devices that are intended to treat or diagnose conditions or diseases that affect small or rare populations.

This pathway involves a two-step process. The FDA must grant a Humanitarian Use Device (HUD) exemption and the device company must then submit an HDE application to the appropriate review center.

Another important requirement is that there cannot be another comparable device on the market that shares the same intended use. The FDA will consider the following when determining if there are comparable devices on the market:

- The device's indications for use and technological characteristics.
- The patient population to be treated or diagnosed with the device.
- Whether the device meets the needs of the identified patient population.

Part of the rationale for providing this pathway is there may not be a large enough patient population with clinical data to satisfy regular FDA requirements of safety and efficacy. Since these devices may be very crucial to patients with rare conditions, the FDA put them in place to do a proper review to determine if the device can be sold.

5.) Custom Device Exemption (CDE)

Is the company developing a custom device for a specific patient? If so, the device falls under the Custom Device Exemption (CDE) pathway and must meet a very narrow set of criteria.

The device must be created or modified to comply with the order of an individual physician or dentist, typically in the form of a prescription. Not only must the clinician order the device, but it must also be used in the normal course of the professional practice of that physician or dentist.

The product should be specifically designed to treat a unique pathology or physiological condition that no other device is domestically available to treat. It must be assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of the patient.

The FDA even states that companies are limited to no more than 5 units per year of a particular device type.

CDE devices are exempt from PMA or 510(k) submission process, but the company still needs to comply with the following regulations:

- Design Controls (21 CFR Part 820)
- Medical Device Reporting (21 CFR Part 803)
- Labeling (21 CFR Part 801)
- Corrections and Removals (21 CFR Part 806)
- Registration and Listing (21 CFR Part 807)

6.) Expanded Access Program (EAP)

The Expanded Access Program, often referred to as the compassionate use or emergency use provision, is fairly self-explanatory.

It allows an investigational device to be used, outside of a clinical trial, in situations where a seriously ill patient has few if any alternatives.

Although there are often ethical considerations, it may be appropriate to evaluate this option to get early feasibility data for high-risk devices, especially when suitable animal models are unavailable. Like the HDE, this data could then be used to expand the label in the future.

Expanded access may be an appropriate pathway for you to choose when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment. Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

7.) Product Development Protocol (PDP)

The Product Development Protocol (PDP) is a subset of the PMA process that allows for another pathway for companies with devices in which the technology is well established in the industry.

This pathway allows the company to come to an early agreement with the FDA about how the safety and effectiveness of the device will be shown. The two parties are essentially creating a contract that describes design and development activities, including the outputs of these activities, and acceptance criteria for these outputs.

The company can follow the plan on its own time and report back to the FDA on the agreed-upon milestones. At the end of the process, the company is considered to have "completed" a PDP, which gives them an "approved" PMA.

A managing sponsor of fundraising efforts for the affiliated companies of the PFD family of companies, PFD Capital Partners, Inc. provides capital formulation, management, and portfolio administrative services.

An operational Class A member and manager to the PFD Family Private Equity programs.

PFD Management, LLC is a vendor to the PFD family of private funds, specializing in sourcing, diligence, underwriting, auditing, packaging, servicing, billing/collecting, and portfolio administration of account receivables.

A medical account receivables and medical technology finance fund offering a fixed rate return with additional equity participation in targeted new medical technology opportunities.

SAFE HARBOR DECLARATION

THE STATEMENTS, PROJECTIONS AND ESTIMATES OF FUTURE PERFORMANCE OF THE COMPANY OR VARIOUS ELEMENTS OF THE COMPANY'S BUSINESS CONTAINED IN THIS MEMORANDUM THAT ARE NOT HISTORICAL FACTS ARE FORWARD-LOOKING STATEMENTS. INVESTORS SHOULD EXPECT THAT ANTICIPATED EVENTS AND CIRCUMSTANCES MAY NOT OCCUR, THAT UNANTICIPATED EVENTS AND CIRCUMSTANCES WILL OCCUR, AND THAT ACTUAL RESULTS WILL LIKELY VARY FROM THE FORWARD-LOOKING STATEMENTS. INVESTORS SHOULD BE AWARE THAT A NUMBER OF FACTORS COULD CAUSE THE FORWARD-LOOKING STATEMENTS OR PROJECTIONS CONTAINED IN THIS MEMORANDUM OR OTHERWISE MADE BY OR ON BEHALF OF THE COMPANY TO BE INCORRECT OR TO DIFFER MATERIALLY FROM ACTUAL RESULTS. SUCH FACTORS MAY INCLUDE, WITHOUT LIMITATION, (i) THE ABILITY OF THE COMPANY TO COMPLETE THE DEVELOPMENT OF ITS PRODUCTS IN A TIMELY MANNER, (ii) THE DEMAND FOR AND TIMING OF DEMAND FOR SUCH PRODUCTS, (iii) COMPETITION FROM OTHER PRODUCTS AND COMPANIES, (iv) THE RESULTS OF THE COMPANY'S SAFETY AND EFFICACY STUDIES, (v) THE RESULTS OF THE REGULATORY APPROVAL PROCESS, (vi) THE COMPANY'S SALES AND MARKETING CAPABILITIES, (vii) THE COMPANY'S ABILITY TO SELL ITS PRODUCTS PROFITABLY, (viii) THE ABILITY OF THE COMPANY'S THIRD-PARTY SUPPLIERS TO PROVIDE PRODUCTS AND SERVICES IN A RELIABLE MANNER; (ix) AVAILABILITY OF ADEQUATE DEBT AND EQUITY FINANCING, AND (x) GENERAL BUSINESS AND ECONOMIC CONDITIONS. THESE IMPORTANT FACTORS AND CERTAIN OTHER FACTORS THAT MIGHT AFFECT THE COMPANY'S FINANCIAL AND BUSINESS RESULTS ARE DISCUSSED IN THIS MEMORANDUM UNDER "RISK FACTORS." THERE CAN BE NO ASSURANCE THAT THE COMPANY WILL BE ABLE TO ANTICIPATE, RESPOND TO OR ADAPT TO CHANGES IN ANY FACTORS AFFECTING THE COMPANY'S BUSINESS AND FINANCIAL RESULTS.