March 27, 2025

restor3d, inc.
Brianna Prindle
Director of Regulatory Affairs
4001 NC 54, Suite 3160
Durham, North Carolina 27709

Re: K243768
Trade/Device Name: iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OIY, OOG
Dated: January 10, 2025
Received: January 10, 2025

Dear Brianna Prindle:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243768

Device Name
iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System

Indications for Use *(Describe)*
The iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:
• Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
• Post traumatic loss of joint function.
• Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
• Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
• Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

This implant intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

The CS (cruciate sacrificing) insert option should be utilized when additional anterior-posterior constraint is desired.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System Traditional 510(k)

510(k) Number:	K243768
Submitter's Name and Address	restor3d, inc. 4001 NC 54, Suite 3160 Durham, NC 27709 USA
Main Telephone Number:	786-521-0501
Establishment Registration:	3014833750
Manufacturing Address	600 Research Dr Wilmington, MA 01887 USA
Manufacturing Establishment Registration:	3004153240
Date Summary Preparation:	March 25, 2024
Subject Device: (Proprietary /Trade Name)	iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System
Common Usual Name	Knee Replacement System
Type of Submission:	Traditional
Regulatory Class	Class II
Regulation Number(s):	21 CFR 888.3565 21 CFR 888.3560
Regulation Description(s):	• Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis • Knee joint patellofemorotibial polymer/metal/polymer semiconstrained cemented prosthesis
Product Classification Code(s) and Description(s)	**MBH**: prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer **JWH**: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer **OIY:** prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive **OOG**: knee arthroplasty implantation system.
Reviewing Agency/Panel	Orthopedic
Contact Name:	Brianna Prindle
Title:	Director of Regulatory Affairs
Contact Telephone:	(c) 786-521-0501
Contact email:	brianna@restor3d.com

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Primary Predicate 510(k):	K223316
Primary Predicate Device:	Identity™ Imprint™ Porous Cruciate Retaining Knee Replacement System
Regulatory Class	Class II
Regulation Number(s):	21 CFR 888.3565 21 CFR 888.3560
Regulation Description(s)	• Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis • Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Primary Predicate Device Product Classification Code(s) and Description(s):	**MBH**: prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer **JWH**: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer **OIY:** prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive **OOG**: knee arthroplasty implantation system.
Secondary Predicate 510(k):	K230846
Secondary Predicate Device:	iTotal® Identity™ Cruciate Retaining Knee Replacement System
Regulatory Class	Class II
Regulation Number(s):	21 CFR 888.3560
Regulation Description(s)	• Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Secondary Predicate Device Product Classification Code(s) and Description(s):	**JWH**: prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer **OIY:** prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer + additive/metal/polymer + additive **OOG**: knee arthroplasty implantation system.
Reference 510(k):	K232595
Reference Device:	restor3d Kinos Axiom Total Ankle System
Regulatory Class	Class II
Regulation:	21 CFR 888.3110
Regulation Description	Ankle joint metal/polymer semi-constrained cemented prosthesis
Reference Device Product Classification Code(s) and Description(s):	HSN Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer
Secondary Reference 510(k):	K240591
Secondary Reference Device:	restor3d Kinos Axiom Total Ankle System
Regulation:	21 CFR 888.3110
Regulatory Class	Class II
Regulation Description	Ankle joint metal/polymer semi-constrained cemented prosthesis
Reference Device Product Classification Code(s) and Description(s):	HSN Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer

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Indications for Use
The iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:
- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

This implant intended for uncemented use, but porous implants may be used with cement if desired by the surgeon.

The CS (cruciate sacrificing) insert option should be utilized when additional anterior-posterior constraint is desired.

Device Description:
The iTotal® Identity™ Cruciate Retaining 3DP Porous Knee Replacement System is a tricompartmental semi-constrained knee prosthesis composed of three components: a Femoral Component, a Tibial Component, and a Patellar Component. The product design incorporates a bone preserving approach for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. The joint restoring design provides for more natural kinematics by maintaining the patient specific femoral sagittal curves, preserving the patient specific femoral offset, preserving the medial and lateral joint lines and having a patient specific fit. It is intended for use in those patients whose condition cannot be appropriately or effectively addressed using a device that treats only one or two compartments of the knee (i.e. a unicompartmental, bicompartmental, or patellofemoral prosthesis).

Using patient imaging (CT scans), a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The treatment allows for the placement of an uncemented metallic device designed from the patient's natural bone geometry. The femoral component is additively manufactured from a cobalt chromium molybdenum ("CoCrMo") alloy. The tibial tray is additively manufactured from titanium ("Ti-6Al-4V") alloy. The tibial inserts are manufactured and offered in either ultra-high molecular weight polyethylene (iPoly®) or highly cross-linked ultra-high molecular weight Vitamin-E enriched polyethylene (iPoly® XE). The patellar component is manufactured and offered in ultra-high molecular weight polyethylene (iPoly®) with a porous Ti6Al4V metal backing. The femoral, tibial, and patellar implants are additively manufactured using proprietary TIDAL Technology™ which allows biological fixation without the need for bone cement. The iTotal® Identity™ CR 3DP Porous KRS is designed for press-fit use without cement, but may be used with a cemented technique if desired.

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The iTotal® Identity™ CR 3DP Porous KRS is supplied with disposable, patient-specific instrumentation (iJig®) designed for use with the system. These patient-specific guides are pre-navigated to fit the contours of the patient's femoral and tibial anatomies and to facilitate a simpler surgical technique. Each set of instruments is designed for one-time use, specifically for one patient. The iJig® instrument set is manufactured from biocompatible nylon material and supplied sterile along with the implants.

Technological Characteristics:
The subject device is designed for cementless fixation which is the same as the primary predicate device which features a porous coating. The subject device has a similar design to the primary predicate, however the subject device is additively manufacturing using and integrally built TIDAL porous surface lattice. The subject device components, femoral component, tibial tray, tibial insert and patella have the same functional specifications as the secondary predicate device components, iTotal Identity CR KRS, however the subject device is designed for cementless fixation instead of cemented fixation. Additionally, the subject device uses the same material, packaging and sterilization as the secondary predicate device.

The subject device components, femoral component, tibial tray and patella backing are additively manufactured of the same materials with TIDAL deign with gyroid-sheet lattice designed for osseointegration on bone-contacting surfaces as the reference devices restor3d Kinos Total Ankle System.

Non-Clinical Performance Evaluation:
- Patella static tensile test
- Patella static shear test
- Patella shear fatigue test
- Tibial tray fatigue test
- Femoral fatigue test
- Tibial micromotion
- Tibiofemoral constraint test
- Tibiofemoral contact area, stress and wear test
- Tibial interlock test
- Patellofemoral subluxation, contact area and stress test
- Particle characterization
- Porous coating testing per FDA guidance on modified metallic surfaces
- Biocompatibility assessment

Clinical Testing:
No clinical testing was warranted for the subject device.

Conclusion:
The results of the testing demonstrate that the subject device iTotal® Identity™ CR 3DP Porous KRS is as safe and effective and is substantially equivalent to the cleared predicates, Identity™ Imprint™ Porous CR KRS and iTotal Identity CR KRS, and the differences between the subject and predicates do not raise different questions of safety or effectiveness.