April 27, 2026

NovoSource
Doug Hawkins
Official Correspondent
1000 Hampton Center Suite A
Morgantown, West Virginia 26505

Re: K261032
Trade/Device Name: NovoKnee (SteriKnee)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 30, 2026
Received: March 30, 2026

Dear Doug Hawkins:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261032

Device Name
NovoKnee (SteriKnee)

Indications for Use *(Describe)*
The NovoKnee Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. The NovoKnee Total Knee System may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. The NovoKnee Total Knee System is designed for cemented use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #:

510(k) Summary

Prepared on: 2026-04-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NovoSource
Applicant Address	1000 Hampton Center Suite A Morgantown WV 26505 United States
Applicant Contact Telephone	4129996714
Applicant Contact	Mr. Doug Hawkins
Applicant Contact Email	ra@novosource.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NovoKnee (SteriKnee)
Common Name	Semi-constrained total knee prosthesis
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulation Number	888.3560
Product Code(s)	JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K131398	NovoKnee Total Knee System	JWH
K093806(Reference)	MyKnee Cutting Blocks	JWH

Device Description Summary

21 CFR 807.92(a)(4)

The NovoKnee Total Knee System is an implant system that is cleared for use in total knee replacement surgery consisting of femoral implants, tibia trays and inserts. This 510k introduces single-use, manual instruments compatible with the NovoKnee implants.

The SteriKnee™ System is a sterile, single-use set of orthopedic manual surgical instruments intended to prepare bone and facilitate implantation of the NovoKnee Total Knee System. The system is provided pre-assembled and procedure-ready, eliminating the need for reusable instrument trays and intraoperative assembly. The SteriKnee instruments are substantially equivalent in design, function, and dimensions to corresponding reusable orthopedic surgical instruments commonly used in total knee arthroplasty. The system is packaged in a sterile, double-barrier configuration and is intended for single-patient use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The NovoKnee Total Knee System is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. The NovoKnee Total Knee System may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. The NovoKnee Total Knee System is designed for cemented use only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The predicate implants remain unchanged per this submission. The subject device is a set of single-use orthopedic surgical instruments intended to be used in place of predicate reusable instrumentation to prepare bone and facilitate implantation of total knee prosthetic components. The intended use of the subject instruments are the same as that of the predicate instruments.

Technological Comparison

21 CFR 807.92(a)(6)

The SteriKnee™ System has the same fundamental design characteristics and operating principles as reusable orthopedic surgical instruments used in total knee arthroplasty. The instruments perform the same functions and are used in the same manner as predicate instrumentation systems.
The primary technological difference is that the SteriKnee system is provided as a sterile, single-use, pre-assembled instrumentation kit rather than reusable instruments requiring cleaning, sterilization, and assembly. This difference does not raise different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical performance testing was conducted on the subject instruments to support the substantial equivalence of the SteriKnee™ System. Testing included mechanical and functional verification, packaging validation, and sterilization validation in accordance with applicable standards and guidance.
Packaging validation was performed in accordance with ISO 11607 and included seal strength, package integrity, and visual inspection testing. Sterilization validation was conducted using ethylene oxide (EtO) to achieve a sterility assurance level (SAL) of 10^{-6}.

No clinical studies were required to support substantial equivalence.

Conclusion: The results of non-clinical testing demonstrate that the SteriKnee System instruments demonstrate substantial equivalence to the legally marketed predicate device instruments with respect to intended use, materials and performance.