December 20, 2019

NanoOrtho, LLC
Andy Rynearson
Vice President Quality & Regulatory
860 Oak Park Blvd STE 301
Arroyo Grande, California 93420

Re: K190633
Trade/Device Name: NanoOrtho NanoKnee® System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX, HRY, NJD
Dated: November 19, 2019
Received: November 20, 2019

Dear Andy Rynearson:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ting Song
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190633

Device Name
NanoOrtho NanoKnee® System

Indications for Use *(Describe)*

The NanoOrtho NanoKnee® System is indicated for restoring either compartment of a knee that has been affected by the following:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of femoral deformity;
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques.

The NanoOrtho NanoKnee® System components are single use and are intended for implantation with or without bone cement.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6. 510(k) Summary

The following 510(k) Summary is provided in accordance with 21 CFR 807.92.

6.1 510(k) Owner and Registration

Owner's Name:	NanoOrtho, LLC.
Address:	860 Oak Park Blvd., Ste 301, Arroyo Grande, CA 93420
Phone Number:	(805) 714-8984
Fax Number:	(855) 710-7338
Date Summary Prepared:	March 8, 2019
Establishment Registration Number:	N/A

6.2 510(k) Contact

Contact:	Andy Rynearson
Address:	860 Oak Park Blvd., Ste 301, Arroyo Grande, CA 93420
Phone Number:	(321) 316-2601
Fax Number:	(855) 710-7338
Contact Person:	Andy Rynearson

6.3 Device Name and Classification

Device Trade Name:	NanoOrtho NanoKnee® System
Device Common Name:	Unicondylar Knee
Regulation Number and Description:	21 CFR 888.3520
Device Class:	Class II
Product Codes:	HSX, HRY, NJD
Advisory Panel:	87 (Orthopedic)

6.4 Legally Marketed Predicate

NanoOrtho is utilizing the Smith & Nephew Journey Unicondylar Knee System (K073175) as the primary predicate device. Additionally, NanoOrtho is utilizing the Mako Restoris Porous Partial Knee System (K133811) as a predicate device. The NanoOrtho NanoKnee® System features component designs, materials, indications, and manufacturing methods that are substantially equivalent to the predicate device systems.

6.5 Device Description

The NanoOrtho NanoKnee® is a unicompartmental knee system that includes porous coated and non-porous coated, cast CoCr, symmetric femoral components in sizes 1-6; and Ti6Al4V, symmetric, porous coated and non-porous coated tibial baseplate components in sizes 1-6. The tibial inserts are offered in standard UHMWPE, symmetric design, Constrained or Constrained+, in sizes 1-6 and 5 thicknesses per size 9,10,11,12,14mm.

6.6 Intended Use

The NanoOrtho NanoKnee® System indications for use are similar to the predicate Mako Restoris Porous Partial Knee System (K133811) & Smith & Nephew Journey Unicondylar Knee System (K073175).

The NanoOrtho NanoKnee® System is indicated for restoring either compartment of a knee that has been affected by the following:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of femoral deformity;
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques.

The NanoOrtho NanoKnee® System is designed for single use and are intended for implantation with or without bone cement.

6.7 Summary of Technological Characteristics

The NanoOrtho NanoKnee® system is similar to the predicate Mako Restoris Porous Partial Knee System (K133811) & Smith & Nephew Journey Unicondylar Knee System (K073175). These devices are manufactured from the same materials, possess the same size ranges. Extensive preclinical testing was performed on the NanoOrtho NanoKnee® system and found substantially equivalent to the predicate devices. The performance tests are listed below and used herein to establish substantial equivalence (Section 19 Performance Testing – Bench)

6.8 Performance Testing

The results confirm that all components of the NanoOrtho NanoKnee® System are substantially equivalent to the predicate devices.

- Fatigue performance of the tibial tray (ASTM F3140-17)
- Interlock mechanism strength of the tibial tray and insert (ASTM F2083-12)
- Tibiofemoral contact area and stress (ASTM F2083-12)
- Tibiofemoral constraint (ASTM F1223-14)
- Range of motion (ASTM F2083-12)

6.9 Conclusions

The NanoOrtho NanoKnee® System has similar design features, materials, and indications for use as the predicate devices.

The NanoOrtho NanoKnee® System is substantially equivalent to the predicate devices.