DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 27, 2017

Smith & Nephew, Inc.
Ms. Kathleen Solomon
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K171794
Trade/Device Name: Smith & Nephew DYONICS 25 Fluid Management System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: June 14, 2017
Received: June 16, 2017

Dear Ms. Solomon:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171794

Device Name
Smith & Nephew DYONICS 25 Fluid Management System

Indications for Use *(Describe)*
The Smith & Nephew DYONICS 25 Fluid Management System is indicated for use during arthroscopic joint surgery to regulate flow of irrigation fluids in the knee, shoulder, hip, and small joints to maintain intra-articular pressure for uniform distension and clear visualization of the surgical site.

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."

Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810
USA

T 978-749-1000
F 978-749-1443
www.smith-nephew.com

We are smith&nephew

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew DYONICS 25 Fluid Management System

Date Prepared: June 26, 2017

Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road, Andover MA. 01810

Company Contact:

Kathleen Solomon

Sr. Regulatory Affairs Specialist

T 978-749-1605

F 978-749-1443

Device Name

Trade Name:	Smith & Nephew DYONICS 25 Fluid Management System
Common Name:	Arthroscopic Fluid Management System
Classification Name:	Arthroscope
Regulatory class:	II
Product Code:	HRX

Predicate Devices

The Smith & Nephew DYONICS 25 Fluid Management System is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew DYONICS 25 Fluid Management System-K051326.

Description of Device

The Smith & Nephew DYONICS 25 Fluid Management System is a centrifugal fluid management pump used in arthroscopic surgery to regulate the flow of irrigation fluids through the joint to maintain intra-articular pressure for distension and visualization of the surgical site. This is accomplished using an electronic pressure control feedback loop between the control unit and the tube set cassettes.

The Smith & Nephew DYONICS 25 Fluid Management System includes –

- control unit
- inflow tube set
- inflow /outflow tube set
- inflow/outflow tube set with forked suction lines
- day-tube set
- patient tube set
- wired/wireless (IR) remote control (optional)
- Luer to colder Connector (optional)

Additionally, the Smith & Nephew LEVELERT II Fluid Level Sensors (K060123) as well as a shaver system interface cable, U.S. and international power cords can be used with the Smith & Nephew DYONICS 25 Fluid Management System (DYONICS 25).

Intended Use

The Smith & Nephew DYONICS 25 Fluid Management System is intended for use during arthroscopic joint surgery to regulate flow of irrigation fluids to maintain intra-articular pressure for uniform distension and clear visualization of the surgical site.

Comparison of Technological Characteristics

The design changes to the modified Smith & Nephew DYONICS 25 Fluid Management System include updated printed circuit boards (PCBs), new touch-screen LCD display, updated operating system, drivers and software updates. The modified Smith & Nephew DYONICS 25 Fluid Management System has the following similarities as the predicate device cleared in K151326. In that:

- The same indications for use/intended use.
- Utilizes the same principle of operation and fundamental scientific technology
- Incorporates the same basic design
- Incorporates the same material

There are no major differences between the modified Smith & Nephew DYONICS 25 Fluid Management System and the currently cleared predicate.

Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810
USA

T 978-749-1000
F 978-749-1443
www.smith-nephew.com

We are smith&nephew

Performance Data

Testing demonstrated that the Smith & Nephew DYONICS 25 Fluid Management System has met the performance specifications and therefore, is substantially equivalent to the predicate device cleared in K051326.

The following performance data and validations were conducted:

- Package/Performance Testing
- Environmental Testing
- Fluids Testing
- EMC Testing
- Safety Testing
- Software Verification &Validation

The Smith & Nephew DYONICS 25 Fluid Management System meets the following FDA recognized consensus standards:

- IEC 60601-1-2:2015 Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 62304 Medical Device Software - Lifecycle:2006

Conclusion:

The Smith & Nephew DYONICS 25 Fluid Management System met all specified criteria and did not raise new safety or effectiveness questions. The substantial equivalence of the modified device is based on same indications for use, fundamental technology including design, and operational principles. Based on the similarities to the predicates and the performance data, the Smith & Nephew DYONICS 25 Fluid Management System is substantially equivalent to its predicate (K051326).