510(k) Summary
Smith & Nephew, Inc. TRUCLEAR Morcellator System and TRUCLEAR Morcellators

Submitted by: Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810

Date of Summary: December 11, 2013

Contact Person and Address: Bradley Heil, Regulatory Affairs Specialist
T (901) 399-6339 F (901) 566-7831

Name of Device(s): Smith & Nephew, Inc. TRUCLEAR Morcellator System

Common Name: Hysteroscopes and Accessories

Device Classification Name and Reference: 21 CFR 884.1690 Hysteroscopes and Accessories– Class II

Device Class: Class II

Panel Code: Obstetrics and Gynecological

Product Code: HIH

Predicate Devices

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	TRUCLEAR Morcellator System	K110038	03/30/2011
Smith & Nephew, Inc.	TRUCLEAR Incisor Plus Blade 2.9	K103389	03/25/2011
Smith & Nephew, Inc.	IUR Reciprocating Morcellator	K041774	10/07/2004
Smith & Nephew, Inc.	IUR Morcellation System	K031787	12/02/2003

Device Description
Smith & Nephew's TRUCLEAR Morcellator System and TRUCLEAR Morcellators use mechanical resection to remove endometrial polyps and submucous myomas hysteroscopically from the uterus. Mechanical resection allows the surgeon to have precise control of the locations and extent of tissue resected by drawing the targeted tissue into the cutting window under suction while the inner blade cuts the tissue. There have been no major changes in design or materials in the subject TRUCLEAR Morcellator System or its associated morcellators since their market clearance.

Subject of this premarket notification is modifications to the indications for use for the Smith & Nephew, Inc. TRUCLEAR Morcellator System and its associated morcellators.

Intended Use
The TRUCLEAR System and TRUCLEAR Morcellators are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:
Submucous myomas
Endometrial Polyps
Retained products of conception

The predicate devices listed above are intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps. The new proposed indications reword the general indication and specifically list retained products of conception.

Technological Characteristics
There have been no major changes in design or materials in the subject TRUCLEAR Morcellator System or its associated morcellators since their market clearance. As such, the technological characteristics of the TRUCLEAR Morcellator System or its associated morcellators have not changed.

Performance Data
Clinical literature showcasing the use of the TRUCLEAR Morcellator System and Morcellators support the use of TRUCLEAR for the proposed additional indications.

Conclusion
This Traditional 510(k) Premarket Notification is being submitted to modify the indications for use for the Smith & Nephew, Inc. TRUCLEAR Morcellator System and associated morcellators. Based on the similarities to the predicate components and published articles supporting the additional indications, the devices are substantially equivalent to their predicates.

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

January 29, 2014

Smith & Nephew, Inc.
Bradley Heil
Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

Re: K132015
Trade/Device Name: TRUCLEAR Morcellator System and TRUECLEAR Morcellators
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated (Date on orig SE ltr): November 15, 2013
Received (Date on orig SE ltr): November 18, 2013

Dear Bradley Heil,

This letter corrects our substantially equivalent letter of December 13, 2013.

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number: K132015

Device Name: TRUCLEAR Morcellator System and TRUCLEAR Morcellators

Indications for Use:
The TRUCLEAR System and TRUCLEAR Morcellators are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as:
Submucous myomas
Endometrial Polyps
Retained products of conception

Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2014.01.29 15:28:15 -05'00'