Smith and Nephew Incorporated
Ms. Laura Reynolds
Director Regulatory Affairs
970 Lake Carillon Drive, Suite 110
Saint Petersburg, Florida 33716

Re: K143115
   Trade/Device Name: The VersaJet II Hydrosurgery System
   Regulation Number: 21 CFR 880.5475
   Regulation Name: Jet lavage
   Regulatory Class: Class II
   Product Code: FQH
   Dated: June 11, 2015
   Received: June 12, 2015

Dear Ms. Reynolds:

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” (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 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 yours,

Joshua C. Nipper -S

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
Indications for Use

510(k) Number *(if known)*
K143115

Device Name
The VersaJet II Hydrosurgery System

Indications for Use *(Describe)*
The VersaJet II Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physician's judgment, require sharp debridement and pulsed lavage irrigation.

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

General Information

Submitters Name/Address: Smith & Nephew, Inc.
970 Lake Carillon Drive
Suite 110
St. Petersburg, FL  33716

Establishment Registration Number: 3006760724
Contact Person: Laura Reynolds
Director Regulatory Affairs
Phone Number: (727) 329-7702
Date Prepared: July 8, 2015

Device Description

Trade Name: VERSAJET™ II Hydrosurgery System
Generic/Common Name: Jet Lavage
Classification Name: Jet Lavage, 21 CFR 880.5475
Product Code: FQH

Predicate Device Information

<table>
<thead>
<tr>
<th>Current Device</th>
<th>Predicate Device</th>
<th>510k#</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERSAJET™ II Hydrosurgery System</td>
<td>VERSAJET™ II Hydrosurgery System</td>
<td>K110958</td>
<td>08/01/2011</td>
</tr>
</tbody>
</table>

Device Description

The VERSAJET™ II Hydrosurgery System consists of two basic system components: the reusable power console and the single-use, sterile (Ethylene Oxide) handpiece and tubing assembly. A footswitch is also available for operating the system.

The VERSAJET™ II Hydrosurgery System uses a pressurized stream of sterile fluid to cut, ablate and remove tissue and foreign matter from wounds and to resect and remove material in a variety of surgical applications. The device provides cutting, irrigation and evacuation in the same tool.

The high velocity stream of saline simultaneously washes the tissue surface and vacuums away foreign material from the wound. The fluid acts to tangentially ablate the surface of the tissue and
propel excised tissue and debris out of the wound. The debris and fluid are directed into the handpiece into a flexible tube, which carries the effluent to the drain or collection canister.

The pressure can be adjusted using either the footswitch or a sealed membrane switch on the front panel of the power console. Pressure settings range from 1-10 in factory pre-set increments, with the pressure increasing with each higher setting number, depending on user preference and the needs of a particular application.

Associated accessories include:
- VERSAJET EXACT Handpieces, single-use, sterile, in three configurations
- VERSAJET PLUS Handpieces, single-use, sterile, in three configurations
- Footswitch

**Indications for Use**

The VERSAJET II Hydrosurgery System is intended for wound debridement (acute and chronic wounds, burns), soft tissue debridement, and cleansing of the surgical site in applications in which, in the physician's judgment, require sharp debridement and pulsed lavage irrigation.

**Summary Comparison between New and Predicate Devices**

<table>
<thead>
<tr>
<th></th>
<th>New Device:</th>
<th>Predicate Device:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name:</td>
<td>VERSAJET™ II Hydrosurgery System</td>
<td>VERSAJET™ II Hydrosurgery System</td>
</tr>
<tr>
<td>Indications for Use:</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Environment of use</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>VersaJet II Handpiece</td>
<td>Substantially Equivalent</td>
<td>Substantially Equivalent</td>
</tr>
<tr>
<td>Console case</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Power Supply</td>
<td>Substantially Equivalent</td>
<td>Substantially Equivalent</td>
</tr>
<tr>
<td>Motor</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Transmission</td>
<td>Substantially Equivalent</td>
<td>Substantially Equivalent</td>
</tr>
<tr>
<td>User Interface PCB</td>
<td>Substantially Equivalent</td>
<td>Substantially Equivalent</td>
</tr>
<tr>
<td>User Interface Housing</td>
<td>Substantially Equivalent</td>
<td>Substantially Equivalent</td>
</tr>
<tr>
<td>User Interface Chamber</td>
<td>Substantially Equivalent</td>
<td>Substantially Equivalent</td>
</tr>
<tr>
<td>Method of Sterilization:</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Software</td>
<td>Identical</td>
<td>Identical</td>
</tr>
</tbody>
</table>

510(k)# K110958
<table>
<thead>
<tr>
<th>Modification</th>
<th>Reason For Change</th>
<th>Verification Testing Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saline Bag Spike resin</td>
<td>Obsolete material</td>
<td>Comprehensive verification was completed which demonstrated acceptable device performance; retested biocompatibility</td>
</tr>
<tr>
<td>Retainer Fitting—changed from a metal injection molded part to a machined part; no specification changes</td>
<td>Improve manufacturability of the part</td>
<td>Comprehensive verification was completed which demonstrated acceptable device performance</td>
</tr>
<tr>
<td>Body Pump with Chamfer – increase length of dowel pin component</td>
<td>Length of the dowel pin was increased to assure full engagement between the pump body and retaining fitting; improve manufacturability</td>
<td>Comprehensive verification was completed which demonstrated acceptable device performance</td>
</tr>
<tr>
<td>High Pressure Hose - nylon material resin change</td>
<td>Obsolete material</td>
<td>Comprehensive verification was completed which demonstrated acceptable device performance; retested biocompatibility</td>
</tr>
<tr>
<td>Change to power supply Printed Circuit Board (PCB) layout</td>
<td>Address electrical issues of not turning on</td>
<td>Comprehensive verification and reliability was completed which demonstrated acceptable device performance</td>
</tr>
<tr>
<td>Changes to the oil seals, gasket and compression spring in the transmission</td>
<td>Increase reliability and address oil leakage</td>
<td>Comprehensive verification and reliability was completed which demonstrated acceptable device performance</td>
</tr>
<tr>
<td>Replacing passivation process with electro-polishing of the user interface components</td>
<td>Increase their corrosion resistance</td>
<td>Comprehensive verification and reliability was completed which demonstrated acceptable device performance</td>
</tr>
<tr>
<td>Replace a bronze bushing in the user interface chamber, with a Rulon™ bushing</td>
<td>Eliminate galvanic corrosion</td>
<td>Comprehensive verification and reliability was completed which demonstrated acceptable device performance</td>
</tr>
<tr>
<td>Minor modifications to comply with IEC 60601-1 3rd Edition safety standards</td>
<td>Compliance with safety standard</td>
<td>Device complies with the IEC 60601-1 3rd Edition series of electrical safety standards</td>
</tr>
</tbody>
</table>
Non-Clinical Tests (Bench)

Testing has been conducted to verify the modifications to the VERSAJET™ II Hydrosurgery System meet design specifications and demonstrate substantial equivalence to the predicate device.

The list below summarizes the bench testing undertaken and successfully completed for the VERSAJET™ II Hydrosurgery System device:

- Environmental testing of the device including the extremes of the operating range and under general operating room conditions.
- Reliability testing demonstrating that the modified components improved the reliability of the device.
- Monitoring of aerosols generated through the use of the device outside of the operating room in conditions such as out-patient surgery.
- Performance testing demonstrating that the effective cutting pressure range per console power setting, system priming, console cut off pressure function, and handset insertion, removal, engagement and disengagement forces are substantially equivalent to the predicate.

Biocompatibility on the VersaJet Handpieces has been successfully completed in accordance with applicable parts of ISO 10993 as follows:

- Cytotoxicity
- Skin Irritation
- Sensitization

Device complies with the following standards:

- ISO13485:2003, Medical Devices - Quality Management Systems
- ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices
- ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied Part 1: General requirements.(General)
- ISO 15223-2:2010 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied-Part 2: Symbol development, selection and validation. (General)
- BS EN 980:2008 Graphical Symbols for use in the labeling of Medical Devices
- BS EN 1041:2008 +A1:2013 Information Supplied by the Manufacturer with Medical Devices
- ISO 11135: 2014 Medical Devices - Validation and routine control of ethylene oxide sterilization
• ISO 10993-10:2010 Biological evaluation of medical devices- Part 10:Tests for irritation and skin sensitization

Conclusions

In establishing substantial equivalence to the currently marketed predicate devices, Smith & Nephew, Inc. evaluated the indications for use, materials, technology, product specifications and energy requirements of the device. Performance testing, biocompatibility testing and electrical safety testing has been successfully completed to demonstrate that the VERSAJET™ II Hydrosurgery System is substantially equivalent to the predicate device for the intended use.