K101711

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5. 510(K) SUMMARY

CERULEAU™ Electrosurgical Probe - 510(k) Summary

Submitter:	NuOrtho Surgical, Inc.
Contact:	Roy Morgan, PE, PMP
Date Summary Prepared:	June 30th 2010 JUL - 1 2010
Device Trade Name:	CERULEAU™ Electrosurgical Probe
Common Name:	Electrosurgical Probe
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Code:	21 CFR §878.4400 Product Code: GEI
Equivalent Device(s):	• ArthroCare Arthrowands (K011083) • Stryker SERFAS (K991960) • Mitek VAPR S90 (K002422) • ConMed UltrAblator (K993885) • ConMed Bicap Superconductor™ (K012018)
Device Description:	The CERULEAU™ Electrosurgical Probe is a bipolar device designed to direct radiofrequency energy from an electrosurgical generator into target tissue during arthroscopic and orthopedic surgical procedures. Ceruleau delivers non-ablation, low-level amounts of radiofrequency energy to the treatment site. The radiofrequency energy is delivered via a protected electrode geometry which inhibits direct electrode-to-tissue contact. Design of the electrode's protective housing can function as a mechanical implement for use adjunct to energy delivery.
Intended and Indications for Use:	NuOrtho CERULEAU™ Probes are intended for use as surgical instruments. The NuOrtho CERULEAU™ Probes are indicated for resection, coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures. These procedures include the following indications:

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
Resection and Excision	
Acetabular Labrum	Hip
Articular Labrum	All Joints
Capsule	All Joints
Capsular Release	Knee
Cartilage Flaps	Knee
Cysts	All Joints
Discoid Meniscus	Knee
Frozen Shoulder Release	Shoulder
Glenoid Labrum	Shoulder
Labral Tear	Shoulder
Lateral Release	Knee
Ligament	All Joints
Loose Bodies	All Joints
Meniscal Cystectomy	Knee
Meniscectomy	Knee
Plica Removal	All Joints
Sear Tissue	All Joints
Soft Tissue	All Joints
Synovial Membrane	All Joints
Tendon	All Joints
Triangular Fibrocartilage (TFCC)	Wrist
Villusectomy	Knee
Debridement	
ACL/PCL	Knee
Acromioplasty	Shoulder
Articular Cartilage	All Joints
Bursectomy	All Joints
Chondroplasty	All Joints
Facia	All Joints
Ligament	All Joints
Notchplasty	Knee
Scar Tissue	All Joints
Soft Tissue	All Joints
Subacromial Decompression	Shoulder
Synovectomy	All Joints
Tendon	All Joints
Coagulation	
ACL/PCL	Knee
Articular Cartilage	All Joints
Carpal Ligaments	Wrist
Glenohumeral Capsule	Shoulder
Ligament	All Joints
Medial Retinaculum	Knee
Rotator Cuff	Shoulder
Tendon	All Joints
Wrist Tendons	Wrist

Non-clinical Performance Data:

Performance testing per standardized methods and NSI test protocols including bench and *in vitro* human data was conducted and provides support that the CERULEAU™ Electrosurgical Probe is substantially equivalent to currently marketed predicate devices. Non-clinical performance test protocols and results are included in sections 14 through 18 of this 510(k) submission. Test protocols and reports of results demonstrate that, in consideration of its intended use, the design, labeling, packaging and sterilization of the CERULEAU™ Electrosurgical Probe is compliant with the following standards:

- ANSI/AAMI ISO 11137-1:2006 (Cor 1:2007) , Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11607-1:2006-04-15 Packaging for terminally sterilized medical devices —Part 1: Requirements for materials, sterile barrier
- ISO 11607-2: 1st Edition-2006-04-15; Packaging for terminally sterilized medical devices —Part 2: Validation requirements for forming, sealing and assembly processes, including Annex B (informative) listing of standardized test methods and procedures
- ASTM F1980-07; Shelf-life and accelerated aging techniques for standard evaluation of packaging performance
- ASTM D4169 (2009):Standard Test Method for Testing of Shipping Containers and Systems
- ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity.
- ISO 10993-10:2002 (A1:2006), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity.
- ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.
- IEC 60601-1; Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance.
- IEC 60601-2-2- 2009, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment

Section 18, (Bench testing) includes a summary of a comparison study (REP-100-1210) that was conducted to evaluate the effectiveness of the CERULEAU™ Probe performance to other legally available probes intended for similar usage in arthroscopic and orthopedic surgery. The full

report of REP-100-1210 entitled *"Evaluation of Ceruleau™ Performance on Human tissue - Establishment of Clinically Relevant Functional Substantial Equivalence"* is provided in **Appendix 12**.

Section 18 also includes a summary of REP-100-1220 entitled, *"Comparative Evaluation of Ceruleau™ Chondroplasty Performed on Excised Human Articular Cartilage - Assessment of Clinical Efficacy and Extent of Collateral Damage"*, which was conducted in-vitro on excised human tissue and is provided in **Appendix 12**.

The REP-100-1220 provides clear histological evidence to substantiate that, as compared to predicates, the design and use of the CERULEAU™ Probe consistently and significantly reduces incidence of damage to collateral and subject tissues. The study proves that, due to its design, the CERULEAU™ Probe consistently performs to reduce incidence of damage to collateral and subject tissues, while the designs of the predicate devices are inherently prone to cause damage to collateral and subject tissues.

Additionally, Section 21 includes a summary of scientific publications that support the need for the technological features and clinical utility of the CERULEAU Electrosurgical Probe.

Clinical Performance Data:

Clinical data was not necessary to support that the CERULEAU™ Electrosurgical Probe is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL - 1 2010

NuOrtho Surgical, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K101711
Trade/Device Name: Ceruleau™ Electrosurgical Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HRX
Dated: June 17, 2010
Received: June 18, 2010

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number if known: N/A

Device Name: **CERULEAU™Electrosurgical Probe**

The NuOrtho CERULEAU™ Probes are indicated for resection, coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.
These procedures include the following indications:

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Discoid Meniscus	Knee
Frozen Shoulder Release	Shoulder
Glenoid Labrum	Shoulder
Labral Tear	Shoulder
Lateral Release	Knee
Ligament	All Joints
Loose Bodies	All Joints
Meniscal Cystectomy	Knee
Meniscectomy	Knee
Plica Removal	All Joints
Scar Tissue	All Joints
Soft Tissue	All Joints
Synovial Membrane	All Joints
Tendon	All Joints
Triangular Fibrocartilage (TFCC)	Wrist
Villusectomy	Knee
Debridement	
ACL/PCL	Knee
Acromioplasty	Shoulder
Articular Cartilage	All Joints
Bursectomy	All Joints
Chondroplasty	All Joints
Facia	All Joints
Ligament	All Joints
Notchplasty	Knee
Scar Tissue	All Joints
Soft Tissue	All Joints
Subacromial Decompression	Shoulder
Synovectomy	All Joints
Tendon	All Joints
Coagulation	
ACL/PCL	Knee

Mark N Miller
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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Coagulation (continued)	
Articular Cartilage	All Joints
Carpal Ligaments	Wrist
Glenohumeral Capsule	Shoulder
Ligament	All Joints
Medial Retinaculum	Knee
Rotator Cuff	Shoulder
Tendon	All Joints
Wrist Tendons	Wrist

Prescription Use _X_ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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