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APR 30 2009

510(k) Summary
(per 21 CFR 807.87(h))

Common/Usual Name:	Arthroscopic Accessory: Articulating and Extendible Shaver
Product Trade Name:	XTEND-ST™ Nucleus Removal System
Classification Name:	Arthroscope and Accessory Class II per 21 CFR § 888.1100 Product Code HRX
Predicate Device:	Endius, Inc. FlexTip Blade, K022578 Clarus Medical, LLC. Nucleotome Probe Set, K040919 HydroCision, Inc. Arthrojet System, K041233
Manufacturer:	CoreSpine Technologies, LLC 5909 Baker Road, Suite 550 Minneapolis, MN 55345
Contact:	Britt K. Norton Founder and Chief Operating Officer
Date Prepared:	January 30, 2009

Device Description:

The CoreSpine XTEND-ST Nucleus Removal System is a soft tissue removal device that is comprised of a disposable, sterile handheld nucleus tissue cutting device, a table-top electronic control unit, and a foot pedal. The tip of the XTEND-ST cutting device can articulate and extend within the disc cavity providing an ability to reach areas of the disc that are otherwise unreachable with a rongeur. Cut tissue is continuously suctioned through a central lumen using a standard vacuum designed to minimize clogging. The XTEND-ST Nucleus Removal System is intended to effectively and efficiently prepare the disc space without damaging the annulus or endplates in preparation for a spinal implant or other therapy.

The XTEND-ST cutting device is made from a stainless steel rotary cutting mechanism with a motor housed in a plastic handle.

Indications for Use:

The XTEND-ST Nucleus Removal System is intended to resect damaged or diseased nucleus pulposus material found in the adult lumbar disc space.

Comparison of technological characteristics:

Substantial equivalence of the XTEND-ST Nucleus Removal System with the predicate devices is based on similar intended use/indications for use, design, function and materials of construction. The XTEND-ST Nucleus Removal System and the predicate devices are all intended to remove soft tissue during surgery. However, the XTEND-ST cutter tip extends along its axis, whereas the predicate devices do not. Verification and validation studies performed on the XTEND-ST Nucleus Removal System demonstrated that this difference does not negatively affect the safety and performance of the device when used as intended.

Summary of Non-Clinical Testing:

The biological safety of the XTEND-ST cutting device was achieved through the selection of materials that demonstrated appropriate levels of biocompatibility.

Electrical testing was performed on the XTEND-ST Nucleus Removal System per IEC 60601-1 to demonstrate electrical safety, and the result showed the system met the test limits as described for safety testing and conforms to the immunity and emissions requirements for electromagnetic compatibility.

Human factor analysis was conducted and concluded that the XTEND-ST Nucleus Removal System presented acceptable human factors features in both the functioning of the device and usage of the labeling.

Bench testing and cadaver testing were conducted to ensure the performance and safety of the XTEND-ST Nucleus Removal System and to demonstrate substantial equivalent to other commercially cleared tissue removal devices available for sale in the USA.

No new risks or efficacy concerns other than those identified with the predicate device were raised. Results of non-clinical testing demonstrated that the XTEND-ST System is safe and effective for its intended use.

Conclusion:

The XTEND-ST Nucleus Removal System has similar intended use, material biosafety profile, and technical characteristics as the predicate devices. Non-clinical testing was conducted to verify the safety and performance of the XTEND-ST Nucleus Removal System and to ensure the device functions as intended and meets design specifications. As a result, the XTEND-ST Nucleus Removal System has been demonstrated to be substantially equivalent to the predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CoreSpine Technologies, LLC
% Mr. Britt K. Norton
5909 Baker Road, Suite 550
Minneapolis, Minnesota 55345

APR 30 2009

Re: K090303
Trade/Device Name: XTEND-ST™ Nucleus Removal System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: April 13, 2009
Received: April 14, 2009

Dear Mr. Britt:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Current 510(k) Number: K090303

Device Name:

XTEND-ST™ Nucleus Removal System

Indications for Use:

The XTEND-ST Nucleus Removal System is indicated to resect damaged or diseased intervertebral nucleus pulposus material found in the adult lumbar disc space.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K090303

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices