Section 5: 510(k) Summary

FEB - 4 2010

Device Information:

Category	Comments
Sponsor:	Vertos Medical, Inc. 2362 Qume Drive, Suite D San Jose, CA 95131 Tel: 408-437-3101 Fax: 408-437-3108
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Arthroscopic Accessories
Device Classification Number:	21 CFR 888.1100 Arthroscope and Accessories
Device Classification & Product Code:	Class II, HRX
Device Proprietary Name:	Vertos Medical *mild®* Device Kit

Predicate Device Information:

Predicate Device:	X-Sten MILD Tool Kit
Predicate Device Manufacturer:	X-Sten (renamed as Vertos Medical, Inc.)
Predicate Device Common Name:	Arthroscopic Accessories
Predicate Device Premarket Notification #	K062038
Predicate Device Classification:	21 CFR 888.1100
Predicate Device Classification & Product Code:	Class II, HRX

Predicate Device:	Ultra Low Profile Rongeur & Access Tools
Predicate Device Manufacturer:	Baxano, Inc
Predicate Device Common Name:	Manual Rongeur
Predicate Device Premarket Notification #	K062711
Predicate Device Classification:	21 CFR 882.4840
Predicate Device Classification & Product Code:	Class II, HAE

b. Date Summary Prepared
4 February 2010

c. Description of Device
The Vertos Medical *mild®* Device Kit is a set of specialized arthroscopic surgical instruments. They are supplied sterile, for single use only.

d. Indications for Use

The Vertos Medical *mild®* Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

e. Comparison to Predicate Device
The Vertos Medical *mild®* Device Kit is substantially equivalent to the X-Sten MILD Tool Kit (K062038) and the Baxano Ultra Low Profile Rongeur and Access Tools (K062711) in intended use, technology, design and patient contacting materials

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

Company concludes that the devices are substantially equivalent.

f. Summary of Supporting Data
Biocompatibility evaluation demonstrates that the devices are in compliance with ISO 10993.

Bench testing has demonstrated that the devices are in compliance with pertinent standards, the expectations of the medical community and the product labeling.

Cadaveric testing demonstrated that the devices in Vertos Medical *mild®* Device Kit can be used in accordance with the Indications for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB - 4 2010

Vertos Medical, Inc.
% Coombs Medical Device Consulting
Mr. Craig Coombs
President
1193 Sherman Street
Alameda, California 94501

Re: K093062
Trade/Device Name: Vertos Medical *mild*® Device Kit
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HAE
Dated: January 29, 2010
Received: February 01, 2010

Dear Mr. Coombs:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

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

Section 4: Indications for Use Statement

510(k) Number (if known): K 093062

Device Name: Vertos Medical *mild®* Device Kit

Indications For Use:

The Vertos Medical *mild®* Device Kit is a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

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

2/4/10

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

510(k) Number K093062