K062038

Tab 5

Premarket Notification [510(k)] Summary

DEC 19 2006

Trade Name:	**X-Sten MILD Tool Kit**
Common Name:	Arthroscope and Accessories
Classification /Name:	Class II; 21 CFR, part 888.1100 Arthroscope
Device Code:	HRX
Manufacturer's Name: Address:	X-Sten Corp 2362 Qume Drive, Suite D San Jose, CA 95131-1841
Corresponding Official: Title: Address: Telephone:	Timothy M. Reeves Director, Regulatory, Quality and Clinical Affairs 2362 Qume Drive, Suite D San Jose, CA 95131-1841 408-437-3101

Predicate Devices:

K053267	Endius Atavi System
K022578	Endius FlexTip Blade
K991794	Endius Endoscopic Spinal Access System
K983144	Endius Flexposure Retractor
K052241	Ellman International Disc-Fx System
K043602	Medtronic MAST QUADRANT Retractor
K002931	Medtronic METRx
K041123	HydroCision AthroJet Resector XT
K040919	Clarus 21200 Nucleotome Probe Set
K032473	Stryker Dekompressor Percutaneous Discectomy Probe
K002008	Surgical Dynamics Spinal Retractor
K992898	Bright Medical Dilatation Retractor System

Intended Use: The X-Sten MILD Tool Kit is a set of specialized surgical instruments intended to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.

Any statement regarding "substantial equivalence" made in this submission only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any *patent proceeding, including patent infringement, litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.*

Device Description:

The X-Sten MILD Tool Kit is a set of specialized surgical tools for retracting, grasping and excising tissue in the lumbar spine. The kit consists of the following components:

- MILD Tissue Retractor Cobra Device – 8.5 Gauge, 8.5" working length
- MILD Trocars and Handles– 7 Gauge, 6.5" working length
- MILD Portals – 6 Gauge, 6.5" working length
- Surgical Clamp – 14" length

The Trocars, Portals (cannula) and Retractor devices contain stainless steel shafts and plastic handle components. The radiopaque tip and pistol-grip handle aid the user in the Minimally Invasive Lumbar Decompression (MILD) Retractor device positioning and advancement. Under fluoroscopic imaging guidance, the MILD Retractor device is inserted through the Portal into the posterior lumbar spine to retract and grasp tissue. An accessory Clamp can be used to position the Portal and allow handling outside of the fluoroscopic imaging field. A cutting mechanism on the MILD Retractor is advanced by depressing a handle trigger. Excised tissue is removed using an integrated member.

Comparison Table of the X-Sten MILD Tool Kit to the Predicates

Attributes	X-Sten	Clarus Med	Stryker	Hydro-Cision	Ellman Int'l	Bright Med	Surgical Dynamic	Medtronic	Endius
Intended Use	Minimally invasive image-guided tissue resection during decompressive surgery within the lumbar spine.								
Target Population	Products are used for various procedures in patients indicated for spinal decompressive surgery.								
Device Class	Arthroscope					Retractor	Arthroscope; Retractor		
Approach	Percutaneous					Minimally Invasive Portal			
Target Anatomy	Spine / Lumbar	Spine / Disc				Spine / Lumbar			
Imaging	Fluoroscope				Endoscope				Endoscope / Fluoroscope
Materials	Stainless Steel Shafts and Plastic Handles (metal discectomy probes for Stryker)					Stainless Steel Cannula, Dilatators and/or Tissue Resectors			
Action	Retract Grasp Cut	Cut / Aspirate		Ablate Coagulate		Access Retract		Retract Grasp Cut	
Labeling	Sterile Kit, Single-use					Non-sterile, Re-use			Sterile & Non-sterile

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Performance Testing

The X-Sten Mild Tool Kit Retractor and Access instruments passed the designated mechanical test criteria established for the product assemblies. The tests verified the devices have the adequate strength and integrity to safely and effectively perform the stated intended use. Cadaver evaluations demonstrate that tissue can be simultaneously retracted, grasped and excised from the posterior lumbar spine using image guided techniques.

Biocompatibility

The patient contacting stainless steel materials used in the X-Sten MILD Tool Kit were tested for "Externally Communicating Devices, Tissue/Dentin/Bone, Limited Contact", less than 24 hours, as described in ISO 10993 and the FDA Blue Book Memorandum #G95-1. The biocompatibility is substantially equivalent to the predicate devices. The documentation substantiates that the X-Sten MILD Tool Kit Retractor and Access Instruments' patient contacting components fulfill the acceptance criteria for biocompatibility. These results are equivalent to those claimed of the predicates and there were no new types of safety or effectiveness questions.

Sterilization

The MILD Tool Kit is labeled sterile, for single-use only. The packaging and contents will be sterilized with gamma irradiation by a validated process to a Sterility Assurance Level (SAL) of 10^{-6} per AAMI / ISO 11137 and AAMI TIR 27.

Substantial Equivalence

The X-Sten MILD Tool Kit is substantially equivalent in function, technology and intended use to commercially available predicate devices for image guided lumbar spinal decompression procedures. Applicable predicates are identified in the provided comparison table. These include devices for minimally invasive surgery and percutaneous discectomy.

The X-Sten MILD Tool Kit was tested in accordance with 21 CFR 807.87(d - g) to verify substantial equivalence to the predicate devices. The technological comparisons to the predicates support the substantial equivalence of the MILD Tool Kit for its intended use. Combined with the product performance test results and the substantial equivalence discussions, the X-Sten MILD Tool Kit is demonstrated to be substantially equivalent to the predicates. The MILD Tool Kit has the same intended use and similar technological characteristics as the predicate devices. Any differences between the MILD devices and the predicates do not raise any new types of safety or effectiveness questions.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

X-Sten Corporation
% Mr. Timothy M. Reeves
Director of Regulatory, Quality
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2362 Qume Drive, Suite D
San Jose, California 95131-1841

DEC 19 2006

Re: K062038
Trade/Device Name: X-Sten MILD Tool Kit
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: November 27, 2006
Received: November 28, 2006

Dear Mr. Reeves:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062038

Device Name: X-Sten MILD Tool Kit

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 General, Restorative, and Neurological Devices

510(k) Number K062038