K073633

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Kalamazoo, MI 49001
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AUG 2 6 2008

stryker
Instruments

510(k) Summary

Device Sponsor:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 (p) 269-323-7700 (f) 269-324-5412
Registration No.:	1811755
Trade Name:	Stryker ESSx Microdebrider System
Common Name:	Surgical ENT Drill with accessories
Classification Name:	Ear, nose and throat (electric or pneumatic) surgical drill (ERL) Ear, Nose and Throat Bur (EQJ) Blade, Saw, General and Plastic Surgery, Surgical (GFA)
Equivalent to:	K011381 Stryker Hummer IV MicroDebrider K041523 Medtronic XPS 3000 K020594 Gyrus Diego Powered Dissector and Drill
Device Description:	The Stryker ESSx Microdebrider System is a powered instrument system consisting of a console, footswitch, handpiece, irrigation cassette, and a variety of disposable shaver accessories.
Indications for Use:	The Stryker ESSx Microdebrider System is an electrically operated surgical instrument system. The electric motor provides power to operate removable rotating surgical cutting tools intended for the cutting and removal of soft and osseous tissue in general ENT encompassing,the areas of Sinus, Nasopharyngeal /Laryngeal and Head and Neck procedures, such as the following:

Sinus:

- ethmoidectomy/sphenoethmoidectomy
- polypectomy
- septoplasty
- antrostomy
- endoscopic DCR
- frontal sinus drill-out
- frontal sinus trephination
- septal spurs removal
- trans-sphenoidal procedures

Nasopharyngeal/laryngeal:

- adenoidectomy
- laryngeal lesion debulking
- laryngeal polypectomy
- tracheal procedures
- tonsillectomy

Head & Neck:

- soft tissue shaving
- rhinoplasty
- removal of fatty tissue in the maxillary and mandibular regions of the face

Substantial Equivalence (SE) Rational: The Stryker ESSx Microdebrider System has the same intended use as the **Medtronic XPS 3000** and **Gyrus Diego Powered Dissector and Drill**. This device and the predicate devices have the same technological characteristics, the same operating principles, use the same patient contacting materials and have similar performance characteristics.

Safety and Effectiveness: Based upon the comparison to the predicate devices, the Stryker ESSx Microdebrider System is substantially equivalent to legally marketed devices.

Submitted by: Colette O'Connor
Regulatory Specialist

Colette O'Connor
Signature

Date submitted: 21 August 2008

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August 21st, 2008

ATTN: K073633
Food and Drug Administration,
Center for Devices and Radiological Health,
Office of Device Evaluation,
Document mail Center (HFZ-401),
9200 Corporate Boulevard,
Rockville, MD 20850,
USA

Subject: K073633, Stryker ESSx System

Dear Mr. Nandkumar,

The following information is being provided per your request of August 20th 2008. The indications for use statement section of the 510K summary sheet has been revised as requested.

Can you please confirm that you have received this response via e-mail colette.oconnor@stryker.com or by fax to 011 353 21 4532961.

Sincerely,

Colette O'Connor 21 Aug 08
Colette O'Connor, Regulatory Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2008

Stryker® Instruments
c/o Liz Walsh
Carrigtwohill Business & Technology Park,
Carrigtwohill, Co. Cork, Ireland

Re: K073633
Trade/Device Name: Stryker ESSx Microdebrider System
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: II
Product Code: ERL
Dated: July 16, 2008
Received: July 21, 2008

Dear Ms. Walsh:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073633

510(K) Number (if known): _____

Device Name: Stryker ESSx Microdebrider System

Indications for Use

The ESSx Microdebrider System is intended for the cutting and removal of soft and osseous tissue in general ENT encompassing the areas of Sinus, Nasopharyngeal /Laryngeal and Head and Neck procedures, such as the following:

Sinus:

- ethmoidectomy/sphenoethmoidectomy
- polypectomy
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- rhinoplasty
- removal of fatty tissue in the maxillary and mandibular regions of the face

Prescription Use __X__ 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)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K073633