

stryker

K972584

ENDOSCOPY

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CARLOS GONZALEZ
 Vice President of Regulatory
 and Quality Assurance

OCT - 1 1997

Device Name:

Classification Name: Surgical ENT Drill 874.4250, Class II
Common and Usual Name: Electrical Surgical Shaver
Proprietary Name: Stryker Hummer II MicroDebrider System

Device Sponsor:

Stryker Endoscopy
 2590 Walsh Ave.
 Santa Clara, CA 95051
 FDA Registration No. 2936485

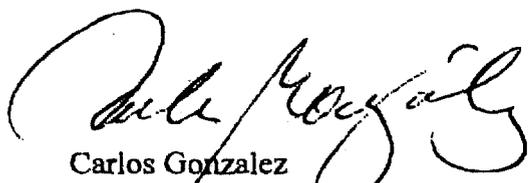
SAFETY AND EFFECTIVENESS SUMMARY:

The Stryker Hummer II MicroDebrider System, consisting of instrumentation which power disposable irrigated cutters and burs, is used in Endoscopic or open plastic, reconstructive and acsthetic surgery of the Head and Neck.

The disposable cutters, burs and tubing sets employed as accessories with the Stryker Hummer II MicroDebrider system, are provided sterile, for single use only, and are validated to an SAL of 10⁻⁶. The materials of construction, cutting action, speed of rotation, availability of suction/irrigation and tip configuration are equivalent to Linvatec blades and or the Xomed shaver system, and patient contact materials are demonstrated to be biocompatible per ISO standard 10993. The accessory devices offer no new safety or effectiveness concerns.

The powered instrumentation technology utilized in the device is equivalent to existing marketed devices and is currently cleared for use in Functional Endoscopic Sinus Surgery under K# 952681. This instrumentation is designed to meet IEC 601-1 electrical standards, as well as UL and CSA requirements.

The Stryker Hummer II MicroDebrider system does not raise any new safety or effectiveness concerns when compared to, and is therefore equivalent to, the Linvatec and Xomed shaver systems.



Carlos Gonzalez
 VP, Regulatory Affairs
 and Quality Assurance



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 1997

Carlos Gonzalez
Vice President, Regulatory Affairs
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, CA 95051

Re: K972584
Stryker Hummer II MicroDebrider System
Dated: July 7, 1997
Received: July 10, 1997
Regulatory Class: II
21 CFR 874.4250/Procode: 77 ERL

Dear Mr. Gonzalez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K # 972584

Device Name: Stryker Hummer II MicroDebrider

Indications For Use:

The Stryker Hummer II MicroDebrider system, is to be utilized for endoscopic or open plastic, reconstructive, and aesthetic surgery of the Head and Neck.

When using the Stryker Hummer II MicroDebrider system, the surgeon has the ability to choose either open or endoscopic viewing and the option to utilize irrigation or vacuum as the surgeon deems necessary. The precise cutting action of the Hummer II Shaver blades allow the surgeon to achieve desired tissue removal, thus minimizing unwanted contour lines, skin discoloration and patient trauma.

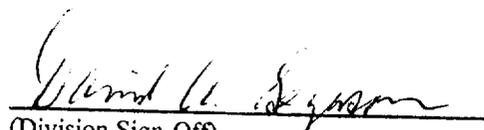
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use


(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972584