2/19/99

stryker®

ENDOSCOPY

2590 Walsh Avenue
Santa Clara, CA 95051

510(k) Summary

K990038

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1. Name: Stryker Endoscopy
2. Address: 2590 Walsh Ave
   Santa Clara, CA 95051
3. Phone number: (408) 567-2176
4. Fax number: (408) 567-2507
5. Contact person: David Himes
6. Summary prepared: 12/30/98
7. Proprietary name: Hummer Trak
8. Common name: Electrical surgical shaver with irrigation.
9. Classification name: Ear, nose, and throat electric or pneumatic surgical drill
10. The Hummer Trak System is equivalent to the Hummer II Microdebrider System (K952681 and K972584).
11. Description: The Hummer Trak System can be sub-divided into two systems, the handpiece and the power unit. The power unit is placed in a secure position, permitting the handpiece to access the surgical site. The power unit contains a motor that drives the handpiece via a flexible drive shaft. Slots are cut in the body of the power unit, permitting lashing straps to secure the unit. The power unit is connected to the TPS Console (K942956 and K943563/S2). The handpiece is mechanically driven from the power unit via the flexible drive shaft. The handpiece effectively transmits the motor energy of the power unit to the shaver blade or bur attachment. A slot is cut longitudinally along the circumference of the handpiece body, securing irrigation tubing. A ball-type valve is provided to regulate suction from the shaver blade or bur attachment. Suction tubing is connected to the handpiece utilizing a suction fitting. A quick release trinkle-type mechanism is used to secure shaver blade and bur attachments. A receiver mount is located on the upper portion of the handpiece body, allowing an image guided sensor to be secured. The InstaTrak image guided sensor is secured to the handpiece by means of a receiver mount. The mount holds the sensor in place by engaging a notch within the sensor and a Delrin latch. The sensor provides three dimensional visualization of the shaver blade or bur attachment's precise location. Small magnets embedded within the receiver mount identify the handpiece as a probe type to the image guided surgery system. Two physical interlocks ensure that calibration is performed when required. Removal of the image guided sensor triggers recalibration when the magnets are no longer

detected. Additionally, a mechanical arm connected to the locking mechanism shifts the magnets, creating an intermittent signal loss, forcing recalibration.

12. Intended use: The device is intended to be utilized during Functional Endoscopic Sinus Surgery (FESS) for the excision of soft and osseous tissues in the sinus cavities. The device may also be utilized for endoscopic or open plastic, reconstructive, and aesthetic surgery of the head and neck. Additionally, the device may be used in conjunction with Visualization Technologies, Inc. (VTI) InstaTrak (K960330) image guided system.

13. Technological characteristic comparison: The Hummer II Microdebrider System (K952681 and K972584) and Hummer Trak System have identical indications for use, excluding the capability of the Hummer Trak System to accept an image guidance sensor. Both devices are driven by the same DC brushless motor and controller. Due to interference with image guided surgery sensors, all electromagnetic materials, including stainless steel and magnets, within the Hummer Trak handpiece had to be minimized or reduced. In order to eliminate interference from the motor rotor magnets, a flexible drive shaft is used to isolate the motor assembly from the handpiece housing. Suction controls are employed in both devices and operate by constricting flow within a channel. Due to space constraints, the Hummer Trak suction operates in a side-to-side fashion. This has no affect on safety and efficacy. The Hummer Trak has a receiver mount, which facilitates attachment of an image guided sensor. The mount features an interlock, which triggers the image guided sensor to force recalibration upon insertion of a new attachment. Both devices accommodate identical attachments. Both devices will be tested to the following standards: IEC 601-1, CSA 601.1, UL 2601, IEC 601-1-2, and MDD 93/42/EEC to ensure electrical, thermal, and radiation compliance and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

David Himes
Stryker Endoscopy
Research and Development Group
2590 Walsh Avenue
Santa Clara, CA 96051

Re: K990038
Hummer Trak System
Dated: December 30, 1998
Received: January 6, 1999
Regulatory class: II
21 CFR 874.4250/Procode: 77 ERL

Dear Mr. Himes:

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 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. 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting 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):_____

Device Name: Hummer Trak System

Indications For Use:

- The device is intended to be utilized during Functional Endoscopic Sinus Surgery (FESS) for the excision of soft and osseous tissues in the sinus cavities.
- The device may be utilized for endoscopic or open plastic, reconstructive, and aesthetic surgery of the head and neck.
- May be used in conjunction with Visualization Technologies, Inc. (VTI) InstaTrak (K960330) image guided system.

(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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990038

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)