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San Jose, CA 95138
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K060085

stryker

Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name:	Stryker Scope Holder
Common and Usual Name:	Endoscope Holder
Classification Name:	Laparoscope, General & Plastic Surgery, Endoscope and/or Accessories

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of the SMDA 1990.

The Stryker Scope Holder is substantially equivalent in terms of safety and effectiveness to currently marketed devices, including the Kronner Low Profile Scope Holder (K000663).

The Stryker Scope Holder is a new product developed by Stryker. The Stryker Scope Holder is an endoscopic accessory, composed of aluminum, stainless steel, PVC and PEEK.

The Stryker Scope Holder is indicated for use in arthroscopic, nasal, abdominal and laparoscopic surgical procedures, including laparoscopic general surgery, thoracic surgery, and endoscopic surgery. The device is intended to hold endoscopes steady in a desired position during the previously mentioned procedures. In addition, the device allows for the rapid repositioning of these endoscopes, laparoscopes and accessories during these procedures.

The Stryker Scope Holder conforms to the following voluntary safety and performance standards: IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety, IEC 60601-2-18 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment, IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests, IEC 60601-1-4 Collateral Standard: Programmable Electrical Medical Equipment, UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety, and EN 554 Sterilization of medical devices Validation and routine control of sterilization by moist heat. In addition, the nitrogen tank will be a DOT 39 non-refillable compressed gas tank. The nitrogen used (ID # UN1066) is an identified material on the Hazardous Materials Table in DOT 49 CFR 172.101 and will adhere to the specified shipping requirements.

There are no significant technological or performance differences between the Stryker Scope Holder and the identified predicate device (Kronner Low Profile Scope Holder (K000663), nor are there any new questions raised regarding safety or effectiveness, therefore, the Stryker Scope Holder is substantially equivalent to the identified predicate devices and surgery systems.

Crystal Ong
Regulatory Affairs Representative

April 11 2006
Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Endoscopy
c/o Ms. Crystal Ong
Regulatory Affairs Representative
5900 Optical Court
San Jose, California 95138

APR 27 2006

Re: K060085
Trade/Device Name: Stryker Scope Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 6, 2006
Received: April 12, 2006

Dear Ms. Ong:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060085

510(k) Number: K060085
Device Name: Stryker Scope Holder

Indications for Use:

The Stryker Scope Holder is indicated for use in arthroscopic, nasal, abdominal and laparoscopic surgical procedures, including laparoscopic general surgery, thoracic surgery, and endoscopic surgery. The device is intended to hold endoscopes steady in a desired position during the previously mentioned procedures. In addition, the device allows for the rapid repositioning of these endoscopes, laparoscopes and accessories during these procedures.

Prescription Use √ OR Over-The-Counter-Use_____
(Per 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 General, Restorative,
and Neurological Devices

510(k) Number K060085