



OCT 2 1998

ENDOSCOPY

2590 Walsh Avenue
Santa Clara, CA 95051

K 982375

(408) 567-9100
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (REVISED)

Applicant: Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, CA 95051
(408) 567-9100

Device Identification: Common Name:
Arthroscope and Accessories
Trade Name:
Stryker Hip Arthroscopy Set

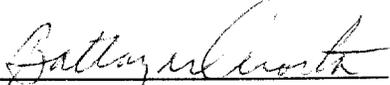
Contact: Baltazar Acosta
Hip Project Coordinator
(408) 567-2433
Carlos Gonzalez
Regulatory Affairs
(408) 567-2179

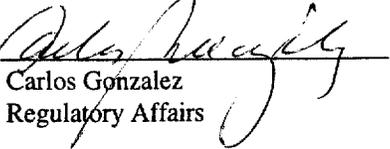
Device Description: The Stryker Hip Arthroscopy Set is composed of reusable instruments including: extended length rigid telescopic arthroscopes and accessories with 30° and 70° oblique view angles, extended length manual surgical instruments made of surgical stainless steel. The instruments are maintained in a hardened plastic tray that accommodate repeat sterilization of the devices. The set is to be used in combination with various styles of Stryker disposable Hip Rotary Surgical Blades.

Indications: The Hip Arthroscopy Set is used for illumination and visualization of the deep confines of the hip joint. The Hip Arthroscopy Set is made size/length appropriate, and is indicated for use in approaching the hip joint for diagnostic evaluation and resection of various diseased soft tissues, debridement of cartilaginous tissues, and the removal of loose and foreign bodies in the hip joint.

Substantial Equivalence Statement: Stryker hip arthroscopes are claimed substantially equivalent (SE) to commercially available arthroscopes made by Karl Storz and cleared under K963524. Stryker hip manual instruments are claimed SE to commercially available devices made by Smith & Nephew, Karl Storz, and Arthrex, cleared under K971253, K963524, and K926212 respectively.

Safety and Effectiveness: The Hip Arthroscopy Set is made size length appropriate, reflecting desirable characteristics as described by orthopedic surgeons now performing various hip arthroscopic procedures. The Stryker Hip Arthroscopy Set introduces no new risks to health as compared with existing commercially available devices.

Signed: 
Baltazar Acosta
Hip Project Coordinator

Signed: 
Carlos Gonzalez
Regulatory Affairs



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1998

Baltazar Acosta
Hip Project Coordinator
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K982375
Trade Name: Stryker Hip Arthoroscropy Set
Regulatory Class: II
Product Code: HRX
Dated: June 2, 1998
Received: July 7, 1998

Dear Mr. Acosta:

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.

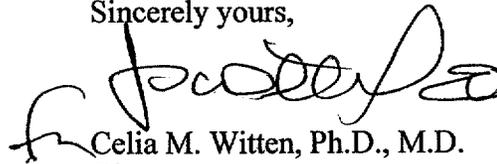
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K982375

Device Name: Stryker Hip Arthroscopy Set

Revised Indications For Use: (Revised)

The Stryker Hip Arthroscopy Set, consisting of reusable instrumentation to access, illuminate and visualize the confines of the hip joint, is indicated for operative and diagnostic arthroscopic procedures of hip joint pathology including evaluation and the removal of loose bodies. Resection of soft, osseous and cartilaginous tissues is possible when used in conjunction with Stryker sterile disposable Rotary Hip Surgical Blades.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over the Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number

K982375