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K081004
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510(k) Summary of Safety and Effectiveness for the
ProtectiScope CS, Non-intrapull Colonoscope

Proprietary Name:	ProtectiScope CS, Non-intrapull colonoscope
Common Name:	Colonoscope and accessories, flexible/rigid
Classification Name and Reference	Endoscope and accessories, 21 CFR §876.1500
Regulatory Class:	Class II
Device Product Code:	78 FDF - colonoscope and accessories, flexible/rigid 87 KOG - endoscope and/or accessories
For Information contact:	Tiffani Rogers Sr. Regulatory Affairs Specialist Stryker GI 1420 Lakeside Parkway #110 Flower Mound, Texas 75028 Phone: (972) 410-7313 Fax: (972) 410-7150 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	April 3, 2008

Device Description

The ProtectiScope CS, Non-intrapull colonoscope is a software controlled device intended for use to visualize the colon to the level of the cecum. The ProtectiScope CS, Non-intrapull colonoscope includes a system control unit, flexible insertion tube, control body, and umbilicus. The insertion tube features a disposable sleeve that is discarded after the colonoscopy procedure is completed.

The ProtectiScope CS, Non-intrapull colonoscope is designed for use in both diagnostic and therapeutic colonoscopy procedures. The insertion tube is designed to accommodate biopsy tools and equipment to remove intestinal polyps and other therapeutic uses.

The design change included in this submission is removal of the air assisted push technology feature of the device. The modified Protectiscope CS, Non-Intrapull device is manually advanced through the large bowel for visualization of the colon.

Intended Use and Indications for Use:

Intended to provide visualization (via a video monitor) and therapeutic access to the lower gastrointestinal tract including, but not limited to the organs, tissues, and subsystems of the large bowel. The device is introduced rectally as with any standard colonoscope, when indications consistent with the requirement for the procedure are observed in adult patient populations.

Substantial Equivalence:

The Protectiscope CS, non-intrapull device included in this submission is a modification to the to the ColonoSight 520B device cleared in K032688. The sole modification is the removal of the air assisted push technology feature of the device. The current design of the Protectiscope CS, non-intrapull device is manually advanced through the colon by the physician like standard colonoscopes. The determination of substantial equivalence is based on the similarities in intended use, design, and general performance to the predicate ColonoSight 520B cleared in K032688.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Ms. Tiffani D. Rogers
Sr. Regulatory Affairs Specialist
Stryker GI
1420 Lakeside Parkway #110
FLOWER MOUND TX 75028

Re: K081004
Trade/Device Name: Protectiscope CS Colonoscope, Non-Intrapull
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: April 3, 2008
Received: April 8, 2008

Dear Ms. Rogers:

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 one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081004

Indications for Use

510(k) Number (if known): K081004

Device Name: Protectiscope CS Colonoscope, Non-intrapull

Indications

Intended to provide visualization (via a video monitor) and therapeutic access to the lower gastrointestinal tract including, but not limited to the organs, tissues, and subsystems of the large bowel. The device is introduced rectally as with any standard colonoscope, when indications consistent with the requirement for the procedure are observed in adult patient populations.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(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,
and Radiological Devices
510(k) Number K081004