

**Section 5:
510(K) Summary**

*K100966
pg 1084*

(As required by 21 CFR 807.92)

Polyurethane Colonoscope/Sigmoidoscope Sheath

July 14, 2010

AUG 3 - 2010

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To Whom it may Concern:

This letter, along with the attached materials is to notify your office of the intention of Sheathing Technologies to market the following device starting on or after (90) days from this date.

Device/Specification Developer: Sheathing Technologies, Inc.
18431 Technology Drive
Morgan Hill, CA 95037

Establishment Registration No.: 2950776

Contact Persons:

Jennifer Downing
Manager of Quality & Research
1-408-782-2720

Richard Stevens
Director of Product Development
1-408-782-2720

Trade Name: Colonoscope/Sigmoidoscope Sheathes™

Common Name: Colonoscope/Sigmoidoscope Sheath

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Classification Name: Colonoscope/Sigmoidoscope Accessory

Equivalence: 510(K) K081004, ProtectiScope CS, Stryker GI (disposable sheath only)
510(K) K032688, Colonosight Model 510B, Sightline Technologies (disposable sheath only)

Labeling and Usage: The following information will be found on each box/bag . (See Section 13, Proposed Labeling):

1. Proprietary name
2. Quantity of sheathes packed
3. Name and Location of Manufacturer
4. Sterile/NS (if applicable)
5. Expiration date
6. Lot number
7. Size of sheath
8. Instructions for use
9. Indications for use
10. Caution statements
11. Prescription Statement

Device Description: The Sheathing Technologies, Inc. Polyurethane Colonoscope/Sigmoidoscope Sheath provides a conformal covering to fit various lengths and widths of colonoscopes and sigmoidoscopes (hereafter referred to as 'endoscopes'). The cover is open at the proximal end to allow free use of the endoscope's channels, and open at the distal end for insertion of the endoscope. Various sizes and shapes of Sheaths are offered to address the variations in size of the endoscopes.

This device is an accessory for use in non-sterile colonoscopy or sigmoidoscopy procedures to help reduce gross contamination of the endoscope, reducing the exposure of staff to gross contamination during the cleaning procedure.

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The cover material is a polyether-blend polyurethane, which is the same blend currently used for Sheathing Technologies probe covers (510(K) K963831 for Sheathes Non-Latex, Non-Sterile and 510(K) K990175 for Sheathes Non-Latex, Sterile).

Product categories/models include

1. Rigid sigmoidoscope Sheaths (sterile and non-sterile)
2. Flexible sigmoidoscope Sheaths (sterile and non-sterile)
3. Colonoscope Sheaths (sterile and non-sterile)

Sheaths are packaged in both sterile and non-sterile, individually wrapped or in bag/box quantities. All are intended for non-sterile procedures, and all are for single patient/procedure, disposable use.

Substantial Equivalence:

The Sheathing Technologies, Inc. Polyurethane Colonoscope/Sigmoidoscope Sheath is identified as substantially equivalent to Stryker GI's current, legally marketed ProtectiScope™ colonoscope Sheath and to Sightline Technologies's current, legally marketed ColonoSight™ colonoscopy Sheath.

Non-Clinical Tests:

1. Bench Testing:
 - a. Stretch testing
 - b. Imperforate seams
2. Biocompatibility
 - a. Cytotoxicity
 - b. Intracutaneous Toxicity
 - c. Sensitization

Conclusions from Non-Clinical Tests: Sheathing Technologies's Polyurethane sigmoidoscope/colonoscope Sheath has sufficient strength and elasticity for the intended application. It is biocompatible

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according to the ISO 10993-1:2003
biocompatibility standard for contact with skin
and mucous membranes for a limited (<24
hour) contact duration.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
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Ms. Jennifer Downing
Manager of Quality & Research
Sheathing Technologies, Inc.
18431 Technology Drive
MORGAN HILL CA 95037

AUG 3 - 2010

Re: K100966
Trade/Device Name: Colonoscope/Sigmoidoscope Sheath
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, ODB
Dated: July 14, 2010
Received: July 19, 2010

Dear Ms. Downing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

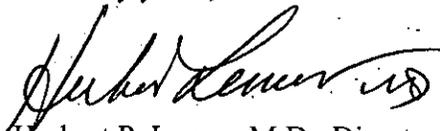
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adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

K100966

Indications for Use Statement

AUG 3 - 2010

510(k) Number (if known): K100966

Device Name: Colonoscope/Sigmoidoscope Sheath

Indication For Use: Colonoscope/Sigmoidoscope Sheaths are meant for use in non-sterile colonoscopy or sigmoidoscopy procedures to help reduce gross contamination of the endoscope, reducing the exposure of staff to gross contamination during the cleaning procedure.

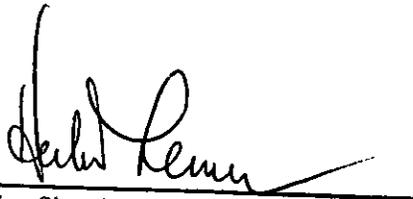
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K100966