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5. 510(k) Summary

Date Prepared May 5, 2006
Revised for ENT/Bronchoscope only May 30, 2006

New Device EndoMedical Technologies Quik-Cover™ Flexible Endoscope Barrier Sheath

Predicate Devices

K000767 Memcath Urology Introducer Sheath
K042531 UPDATED SLIP Urology Introducer Sheath, Percutaneous Systems, Inc.
√ **K990354** Vision-Sciences EndoSheaths for use with Flexible ENT Scopes
K021344 Vision-Sciences Flexible Fiberoptic Bronchoscope and EndoSheath System
K040215 Vision-Sciences Flexible Cystoscope with EndoSheath System
√ **K031786** Vision-Sciences Trans-Nasal Esophagoscope with EndoSheath System
K963344 SS-F32 EndoSheath for use with the Vision-Sciences Model S-F100 Sigmoidoscope

Contact

Marc Jaker, Vice President
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Intended Use

The EndoMedical Technologies Quik-Cover™ Flexible Endoscope Barrier Sheath provides a sterile, disposable protective covering for flexible endoscopes during endoscopic examination of the upper airway, vocal chords, nasal passages, esophagus and pulmonary structures,

Device Description

The EndoMedical Technologies Quik-Cover™ Flexible Endoscope Barrier Sheath (EndoMedical Technologies Quik-Cover™) is a sterile, single-use device that covers the entire patient contact surface of flexible endoscopes and eliminates the need for high-level disinfection of the endoscope following each procedure. The device is composed of a contiguous polymeric sheath, with an optical window at the distal end, which is preloaded on a deployment tube. Some models of the EndoMedical Technologies Quik-Cover™ include a Y-connector and side port channel(s) that are intended to allow passage of air, water, suction and biopsy instruments.

Substantial Equivalence Comparison

The intended use of the EndoMedical Technologies Quik-Cover is similar to the predicate devices in that the sheaths are sterile, disposable protective accessories used to cover endoscopes, catheters or instruments to help prevent the transmission of pathogens.

The EndoMedical Technologies Quik-Cover™ device configuration is similar to the predicate devices in that all devices are comprised of a membrane sheath, a proximal connector and, with respect to the endoscope barrier sheaths, a distal polymeric window. Some models of the EndoMedical Technologies Quik-Cover™ and predicate devices also include a side working channel. The EndoMedical Technologies Quik-Cover application method is similar to the predicate devices in that the sheath slides on and off with no vacuum/ pressure source required.

The EndoMedical Technologies Quik-Cover™ sheath material is identical to the sheath material for the Memcath Urology Introducer Sheath (K000767) and the SLIP Urology Introducer Sheath (K042531) predicate devices. Safety and performance characteristics related to minor design differences have been addressed through the following nonclinical tests:

- Optical qualities of sheath window
- Sheath mechanical tests
- Finished device barrier testing

Nonclinical performance testing demonstrated that the EndoMedical Technologies Quik-Cover™ reliably achieves the desired affect and is safe for its intended use. No new questions of safety or effectiveness for endoscope barrier sheaths were raised during the testing. The EndoMedical Technologies Quik-Cover Flexible Endoscope Barrier Sheath is, therefore, substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Memcath Technologies
c/o Marc Jaker
Vice President
RTC, Inc. – Memcath Technologies, LLC
1777 Oakdale Avenue
West St., Paul, MN 55118-4031

Re: K061663
Trade/Device Name: Quik-Cover Protective Barrier Sheath
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: August 16, 2006
Received: August 17, 2006

Dear Mr. Jaker:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number (if known): K061663

Device Name: EndoMedical Technologies Quik-Cover™ Flexible Endoscope Barrier Sheath

Indications for Use: The EndoMedical Technologies Quik-Cover flexible endoscope barrier sheath provides a sterile, disposable protective covering for endoscopes used during examination of the upper airway, vocal chords, nasal passages, esophagus and pulmonary structures.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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)

sion Sign-Off)
sion of Ophthalmic Ear,
e and Throat Devises
(k) Number K061663

Prescription Use ✓
(Per 21 CFR 801.109)