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Document Date: 5/05/06

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5. 510(k) Summary

Date Prepared May 5, 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
RTC, Inc. - Memcath Technologies, LLC
1777 Oakdale Ave
West St. Paul, MN 55118
Phone: 651-450-7400 Fax: 651-450-7555
Email: mjaker@rtcinemn.com

Intended Use

The EndoMedical Technologies Quik-Cover™ Flexible Endoscope Barrier Sheath provides a sterile, disposable protective covering for flexible endoscopes during endoscopic examination of bladder, urethra, lower gastrointestinal tract, and upper gastrointestinal structures including the esophagus.

Comment: Removed references to ENT and broncho

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.

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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 ir 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

JUN 20 2006

Mr. Marc Jaker
Vice President
RTC, Inc.-Memcath Technologies LLC
1777 Oakdale Ave.
WEST ST. PAUL MN 55118

Re: K061324
Trade/Device Name: EndoMedical Technologies Quik-Cover™ Flexible Endoscope Barrier Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: May 8, 2006
Received: May 18, 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

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

4. Indications for Use Statement

510(k) Number (if known): K061324

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 structures such as the bladder, urethra, lower gastrointestinal tract, and upper gastrointestinal structures including the esophagus.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061324