K063654

SECTION 5
510(k) SUMMARY

510(k) Owner: KMS Medical LLC
7290 SW 42nd Street
Miami, FL
33155
Tel: 305-266-3388
Fax: 305-267-7589

JAN 31 2007

Trade Name:	EndoGuide
Common Name:	EndoGuide Device
Classification Name:	Endoscope and Accessories
Classification Regulation:	21 CFR 876.1500
Class:	II
Product Code:	KOG
Predicate Device:	US Endoscopy Group, Guardus™ Overtube, K040836
Device Description:	The EndoGuide fits over a pediatric colonoscope and can be converted from a flexible to a rigid configuration on demand. The EndoGuide is back loaded onto the shaft of the colonoscope before the instrument is inserted into the patient. The device was designed to be activated by a vacuum source and needs to be connected to the existing vacuum line in the endoscopy suite. Application of vacuum causes the device to become rigid. In this "active" mode (vacuum on) the rigid insertion tube facilitates the passing of the colonoscope thru the insertion tube and resists colonoscope looping. In the "passive" mode (vacuum off) the insertion tube is very flexible and can be advanced deeper into the colon.
Intended Use:	The EndoGuide is intended to be used with an endoscope to facilitate intubation, change of endoscopes, and removal of multiple polyps and/or foreign bodies.
Device Comparison:	The proposed device is similar to the US Endoscopy Guardus™ Overtube. Both devices have identical indications for use. The EndoGuide differs in that it is capable of becoming rigid when required by the physician. When rigid the device facilitates the passing of the endoscope thru the insertion tube and resists endoscopic

looping. But when in its flexible state, the insertion tube is can be advanced into the colon.

Performance Data: To support the substantial equivalence determination, a summary of the in-vitro testing to confirm the performance characteristics in comparison with the predicate device has been submitted.

Summary Prepared by: Mario Arbesu
Director of Product Assurance, KMS Medical LLC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Mario Arbesu
Director of Product Assurance
KMS Medical LLC
7290 S.W. 42nd Street
MIAMI FL 33155

JAN 31 2007

Re: K063654
Trade/Device Name: EndoGuide
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF and KOG
Dated: December 6, 2006
Received: December 13, 2006

Dear Mr. Arbesu:

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 (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 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

SECTION 4
INDICATIONS FOR USE

510(k) Number (if known): ~~TBD~~ K063654

Device Name: EndoGuide

Indications for Use:

The EndoGuide is intended to be used with an endoscope to facilitate intubation, change of endoscopes, and removal of multiple polyps and/or foreign bodies.

Prescription Use ✓ AND/~~OR~~ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063654