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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

1. SUBMITTER INFORMATION

a. Company Name:	USGI Medical
b. Company Address:	1140 Calle Cordillera San Clemente, CA 92673
c. Telephone: Fax:	(949) 369-3890 (949) 369-3891
d. Contact Person:	Mary Lou Mooney Vice President of Clinical, Regulatory & Quality
e. Date Summary Prepared:	August 24, 2007

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	TransPort™ Endoscopic Access Device
b. Common Name:	Endoscopic Overtube
c. Classification Name:	Endoscope and accessories, 876.1500

3. IDENTIFICATION OF PREDICATE DEVICES

TransPort™ Endoscopic Access Device	USGI Medical (K061216)
ShapeLock™ Endoscopic Access Device	USGI Medical (K033954)

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4. DESCRIPTION OF THE DEVICE

The TransPort Endoscopic Access Device is comprised of a flexible shaft that can be rigidized and locked into position, a steerable tip and multiple lumens that allow insertion and exchange of flexible instruments. It is supplied as two separately packaged components, i.e., a reusable, metal body and a sterile, single use disposable sheath.

5. STATEMENT OF INTENDED USE

The TransPort Endoscopic Access Device is intended to be used with an endoscope to facilitate intubation of the endoscope and as a guide for various flexible instruments.

6. COMPARISON WITH PREDICATE DEVICES

The TransPort Endoscopic Access Device is comparable to the predicate devices in terms of intended use, technology, and materials.

Bench testing was conducted to ensure that the device performs as intended when used according to its instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 1 3 2007

Ms. Mary Lou Mooney
Vice President of Clinical, Regulatory & Quality
USGI Medical
1140 Calle Cordillera
SAN CLEMENTE CA 92673

Re: K072405
Trade/Device Name: USGI TransPort™ Endoscopic Access Device
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FED and ODB
Dated: August 24, 2007
Received: August 27, 2007

Dear Ms. Mooney:

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

Indications for Use

510(k) Number (if known): K072405

Device Name: USGI TransPort™ Endoscopic Access Device

Indications For Use:

The USGI TransPort Endoscopic Guide is intended to be used with an endoscope to facilitate intubation of the endoscope and as a guide for various flexible endoscopic instruments.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072405