K061268

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

JUL 3 1 2006

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:	May 4, 2006

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	g-Lix™ Tissue Grasper
b. Common Name:	Grasper
c. Classification Name:	Manual surgical instrument for general use, 878.4800

3. IDENTIFICATION OF PREDICATE DEVICES

EndoPATH Tissue Grasper	Ethicon Endo-Surgery (K930933)
FG Grasping Forcep	Olympus America (K962474)

4. DESCRIPTION OF THE DEVICE

The g-Lix Tissue Grasper is a sterile, single patient use device used for tissue grasping and mobilization. It is comprised of a proximal rotation knob, flexible or rigid shaft and distal helix tip.

5. STATEMENT OF INTENDED USE

The g-Lix Tissue Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and mobilization, especially for tissue which will be removed, such as the gall bladder.

6. COMPARISON WITH PREDICATE DEVICES

The g-Lix Tissue Grasper 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

USGI Medical
% Ms. Mary Lou Mooney
Vice President of Clinical, Regulatory
& Quality
1140 Calle Cordillera
San Clemente, California 92673

Re: K061268
Trade/Device Name: G-Lix Tissue Grasper
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: I
Product Code: HET
Dated: July 18, 2006
Received: July 19, 2006

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.

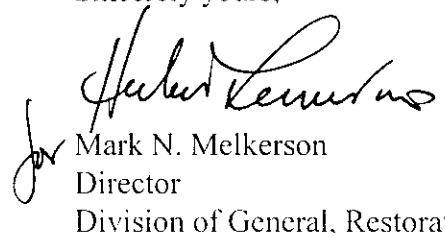
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061268

Device Name: g-Lix Tissue Grasper

Indications For Use:

The g-Lix Tissue Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and mobilization, especially for tissue which will be removed, such as the gall bladder.

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 General, Restorative, and Neurological Devices

510(k) Number K061268