AUG 15 2002

SURGICON, INC.
510(k) NOTIFICATION

K021747

# 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

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| SUBMITTER | Surgicon, Inc.<br>400 Long Beach Blvd. – Stratford, CT 06615 |
| CONTACT PERSON | Curt Raymond |
| DATE PREPARED | May 21, 2002 |
| CLASSIFICATION | Accessory to laparoscope |
| COMMON NAME | Laparoscopic specimen container |
| PROPRIETARY NAME | DeGall Laparoscopic Gallbladder Extractor |
| PREDICATE DEVICES | Auto Suture Endo Catch Specimen Pouch<br>Minogue Xtractor Specimen Retrieval |
| DEVICE DESCRIPTION | The device consists of an introducer and a polyurethane specimen container into which the excised gallbladder is placed. The device, with the specimen held within, is then withdrawn through the abdominal access wound (previously created by the trocar). The device can operate through a variety of access port sizes down to 5mm. The device is manually powered and controlled. It is composed of biologically safe materials. It is supplied sterile and intended for single use only. |
| INTENDED USE | The subject device is intended for the retrieval and removal of the gallbladder in laparoscopic cholecystectomies. |
| TESTING | The device has been subjected to in-vitro and in-vivo testing which demonstrate the ability of the device to withdraw and contain specimens under conditions in excess of those encountered during normal clinical use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2002

Surgicon, Inc.
Curtis Raymond
Director, Regulatory & Quality
400 Long Beach Boulevard
Stratford, Connecticut 06615

Re: K021747
Trade/Device Name: DeGall Laparoscopic Gallbladder Extractor
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCI
Dated: May 24, 2002
Received: May 28, 2002

Dear Mr. Raymond:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K021747

# STATEMENT FOR INDICATIONS FOR USE

The subject device is intended for the retrieval and removal of the gallbladder in laparoscopic cholecystectomies.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021747