DEC 1 9 2003

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

K033359

SUBMITTER	Surgicon, Inc. 400 Long Beach Blvd. – Stratford, CT 06615
CONTACT PERSON	Curt Raymond Director, Regulatory & Quality Surgicon, Inc. 400 Long Beach Blvd. – Stratford, CT 06615
DATE PREPARED	October 16, 2003
CLASSIFICATION	Applicable product code(s): GCI Applicable CFR reference(s): 21 CFR 876.1500 Classification: Class II
COMMON NAME	Laparoscopic specimen container
PROPRIETARY NAME	DeGall II Laparoscopic Gallbladder Extractor
PREDICATE DEVICE	Surgicon DeGall Gallbladder Extractor (K021747)
DEVICE DESCRIPTION	The device consists of a polyurethane specimen container used in conjunction with a stainless steel cone retractor. The excised gallbladder, or other similar tissue specimen, is placed within the specimen bag. The bag is then brought within the confines of the cone retractor. The cone retractor is then used to shield the specimen during trans-abdominal extraction. The device can operate through a variety of trocar 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 device is intended for the retrieval and removal of excised gallbladders, or other similar tissue specimens, during the course of laparoscopic surgery.
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

DEC 1 9 2003

Mr. Curt Raymond
Director, Regulatory and Quality
Surgicon, Inc.
400 Long Beach Boulevard
Stratford, Connecticut 06615

Re: K033359
Trade/Device Name: DeGall II Laparoscopic Gallbladder Extractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 20, 2003
Received: October 21, 2003

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), please contact the Office of Compliance at (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Indications for Use

510(k) Number: K033359

Device Name: Surgicon DeGall II Laparoscopic Gallbladder Extractor

Indications for Use: The device is intended to assist in the retrieval and removal of excised gallbladders, or other similar tissue specimens, during the course of laparoscopic surgery.

Prescription Use: Yes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhan

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