K01 2150

SEP 2 0 2001

510(k) Summary
as required by 807.92(c)
for Patton Endo-Bag™
Prepared July 5, 2001

Submitted by:	Patton Medical Corporation 1000 Westbank Drive, Suite 5A200 Austin, Texas 78746 512 329-0469 Fax 512 328-9113
Contact Person:	Michael T. Patton President
Device Trade Name:	**Patton Endo-Bag™**
Common Name:	Laparoscopic Specimen Retrieval System
Classification:	Laparoscope, General & Plastic Surgery, § 876.1500, Class II
Predicate Devices:	**ENDOPOUCH SPECIMEN RETRIEVAL BAG** (K933104), manufactured by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876. **PLEATMAN SAC SPECIMEN CONTAINER** (K923945) manufactured by Cabot Medical Corp., 2021 Cabot Blvd. West, Langhorne, PA 19047.

Description of Device:

The **Patton Endo-Bag™** is a single-use retrieval bag designed to temporarily contain organs or stones, and facilitate their removal from the patient without contamination during laparascopic surgery.

Intended Use of Device:

The **Patton Endo-Bag™** is a device that is used during laparoscopic procedures to temporarily store and/or remove tissues.

Substantial Equivalence to Predicate Device:

The **Patton Endo-Bag™** is substantially equivalent to the Endopouch Specimen Retrieval Bag (K933104), manufactured by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876, and the Pleatman Sac Specimen Container (K923945), manufactured by Cabot Medical Corp., 2021 Cabot Blvd. West, Langhorne, PA 19047.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Mr. Michael T. Patton
President
Patton Medical Corporation
1000 Westbank Drive, Suite 5A200
Austin, Texas 78746

Re: K012150
Trade/Device Name: Patton Endo-Bag
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 5, 2001
Received: July 10, 2001

Dear Mr. Patton:

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" (21CFR 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,

Susan Walker, MS

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

510(k) Number (if known): K012150

Device Name: Patton Endo-Bag

Indications For Use:

The Patton Endo-Bag is a single-use retrieval bag designed to temporarily contain organs or tissues and facilitates their removal from the patient without contamination, during laparoscopic surgery.

(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

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter Use _____

(Optional Format 1-2-96)

510(k) Number K012150