MAY 27 1999

K990663

510(k) Summary

MEDTECH LIMITED'S INTROMIT™ HAND ACCESS PORT FOR HAND ASSISTED LAPAROSCOPIC SURGERY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Regulatory Counsel to Medtech Limited

Date Prepared: May 4, 1999

Name of Device:

Intromit™ Hand Access Port for Hand Assisted Laparoscopic Surgery

Common or Usual Name:

Surgical Access Port

Classification Name:

Endoscopic Accessory - Extended Laparoscopy Device

Product Code: GCJ

Predicate Devices:

1. Pilling Weck's Dexterity® Pneumo Sleeve and Protector® Retractor;
2. Karl Storz Endoscopy America, Inc.'s trocars and cannulas for endoscopic and laparoscopic procedures;
3. Solos Endoscopy Inc. GS-4300 Cannula and Trocar and GS-4500 Cannula and Trocar;
4. Marlow Surgical Technologies Hasson SAC Cannula;
5. Ethicon, Inc.'s Endopath Trocar; and
6. Innerdyne Medical 'Step" Radical Expansion Obturator/Cannula.

Intended Use

Intromit™ is intended to be used as a port into surgical sites. The Intromit™ is inserted into the patient's abdomen to provide abdominal access for a surgeon's hand while preserving the pneumoperitoneum during laparoscopic surgery.

Principles of Operation

Intromit™ is a hand access port for use in Minimally Invasive Surgery (MIS). The aim of the designers of Intromit™ was to minimize the trauma to the patient while permitting ease of access to an inflated abdomen. By creating a device whereby the incision required is no larger than that necessary to allow passage of the surgeon's hand and forearm, the first criterion has been achieved. The single handed entry method, with no external clamping or sealing mechanism, has ideally achieved the second criterion. The flexible nature of Intromit™ makes it universal in relation to the size of a surgeon's arm and the depth of insertion into the abdomen.

Intromit™ is easy to use. The incise template is used to mark the location and size of the incision and the perimeter of the adhesive flange site. An incision is made through the patient's abdominal wall into the abdominal cavity. The distal end of the inner sleeve is inserted into the abdominal cavity through the incision. The flange is adhered to the patient's skin using the drawn perimeter line as a guide to its application, creating a pressure-tight seal. Insufflation gas is then

administered through the insufflation valve into the access tube, which makes it easier for the surgeon to insert his or her hand through it into the abdomen.

The insufflation pressure forces the walls of the inner sleeve together at two points, which forms pressure-tight seals. The distal end of the inner sleeve contains a taut valve that forces the walls of the sleeve together, creating a seal in the abdominal cavity. In addition, the proximal end of the access tube is tapered to produce a seal between its lip edge and the surgeon's forearm or wrist. The active seal maintains the abdominal pressure by preventing gas from escaping through the mouth of the access tube.

Technological Characteristics

Intromit™ will be sold as a kit that includes a flexible access tube, medical grade adhesive, sterile lubricant and incise template. The access tube consists primarily of an outer sleeve, an inner sleeve, and an adhesive coated flange, which is welded to the distal end of the outer sleeve. The inner and outer sleeves are welded together. The principal components of the access tube are made of polymer film. Intromit™ is packaged into sterile double tyvek pouches and is labeled as a single-patient use device.

Substantial Equivalence

Intromit™ has the same intended use as Pilling Weck's Dexterity® Pneumo Sleeve and Protector® Retractor. Both devices to be inserted into the patient's abdomen to provide abdominal access for a surgeon's hand while preserving the pneumoperitoneum during laparoscopic surgery. Both the predicate device and Intromit™ achieve this in similar fashion: both comprise a flexible polymer sleeve that when adhesively attached to the patients abdomen, form an extension to the abdomen; both have distal and proximal seals and means of affording protection at the incision site; and both utilize similar materials and manufacturing methods in their construction.

Both Intromit™ and Dexterity® are similar in the way in which they retain pneumoperitoneal pressure during laparoscopic surgery in that they are nominally cylindrical, gas impermeable, flexible polymer sleeves with an integral adhesive flange for sealing and attachment to the patients abdomen. Both incorporate two sealing means, (1) a proximal seal for the containment of pressurized gas with a surgeon's arm passing through the device and (2) a distal seal for the containment of pressurized gas in the absence of a surgeon's arm. In addition, both devices contain a mechanism for protection of the mini-laparotomy incision by way of a polymer film barrier that exists between the incision and the access lumen for the surgeon's "gloved" hand and forearm.

Intromit™ also has the same general intended use as its predicate device trocars and cannulas, listed above. As with the Intromit™, these devices are indicated for laparoscopic surgery using gas pressure to distend the abdominal cavity. These predicate devices have similar principles of operation and technological characteristics, namely they provide access into the surgical site and insufflation gas may be administered through several of the predicate devices, in order to maintain abdominal gas pressure.

Performance Data

Both nonclinical and clinical testing have been conducted on Intromit™. Bench testing has been successfully performed on each component of Intromit™ in order to ensure that the components function as intended during use (*i.e.*, tensile strength testing was conducted on the Intromit™'s outer sleeve, inner sleeve, feather valve, flange, and taut valve). The Intromit™ material was also evaluated for its ability to cause skin sensitization in guinea pigs, and no positive skin responses were obtained for any of the guinea pigs. A clinical study was then conducted to compare hand assisted laparoscopic colectomies ("HALC") with the Intromit™ and standard laparoscopic colectomies ("LC") with trocars. Forty four patients were enrolled in the study. This study showed that:

- The overall procedure time for HALC with the Intromit™ is at least as short as the overall procedure time for LC with trocars;
- Patients in the Intromit™ device group are no more likely to convert to open surgery than patients in the LC group;
- No more instrument changes are required for HALC with the Intromit™ than LC with trocars;
- The one death that occurred during the clinical trial was not related to the Intromit™ device;
- The morbidity for HALC with the Intromit™ is equivalent to the morbidity for LC with trocars;
- The direct hospital costs associated with HALC using the Intromit™ are no higher, and possibly lower, than the direct hospital costs associated with LC using trocars;
- The hospital stays for patients who receive HALC with the Intromit™ are equivalent to the hospital stays for patients who receive LC with trocars; and

- The HALC with the Intromit™ has retained one of the major advantages of laparoscopic surgery, *i.e.*, a shorter reconvalescence when compared to open surgery.

Thus, the clinical study shows that the HALC with the Intromit™ are as safe and effective as LC with trocars.

Conclusion

Based on a narrative comparison of the Intromit™, the Dexterity® device, and the trocars as summarized above and the clinical data which also is summarized above, Intromit™ is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

Medtech, Limited
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K990663
Trade Name: Intromit® Hand Access Port for
Hand Assisted Laparoscopic Surgery
Regulatory Class: GCJ
Product Code: II
Dated: March 1, 1999
Received: March 1, 1999

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K990663

Device Name: Medtech Ltd.'s Intromit Hand Access Port

Indications for Use:

The Intromit is inserted into the patient's abdomen to provide abdominal access for the surgeon's hand while preserving the peritoneum 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 Devices
510(k) Number K990663

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)