MAY 31 2001

510(k) SUMMARY

510(k) NUMBER: ~~PENDING~~ K003871

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

CONTACT PERSON: Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: December 12, 2000

NAME OF DEVICE: Laparoscopic Hand Port

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery. (Regulation Number 21CFR 876.1500, Endoscope and accessories).

TRADE NAME: Applied Intromit-GD

PREDICATE DEVICE:

1. Smith & Nephew Handport System (K990414), Smith & Nephew, Inc., Andover, MA.
2. Applied Intromit Laparoscopic Hand Port (K990663), Medtech Ltd., Ireland. Marketed by Applied Medical Resources, Rancho Santa Margarita, CA.

SUMMARY STATEMENT: The Applied Intromit-GD is a laparoscopic hand port designed to provide abdominal access to the surgeon's hand while preserving pneumoperitoneum during laparoscopic surgery. With the use of the Applied Intromit-GD, the surgeon regains the tactile sense and feedback along with the increased hand-eye and instrumentation manipulation capacity of open surgery. The device allows the surgeon multiple passages of the hand to access the surgery site without losing pneumoperitoneum. The Applied Intromit-GD is simple to set up, easy to use and is of a lower profile thereby maximizing comfort.

The Applied Intromit is very simple in design. It consists of an Intromit Gel Seal Cap, a Base Ring, an Incision Template and a Retracting Sheath. The simple design makes installation of the Applied Intromit during clinical use very easy. Using a sterile skin marker an incision line is marked at the surgery site. Once the incision is made the retracting sheath is placed in position. The base ring is then attached to the sheath. To complete the set up the Gel Seal Cap is snapped onto the base ring. The sterile lubricant is provided to lube the surgeons gloved hand and the port of the Gel Cap to make insertion of hand into the port easy.

The Applied Intromit-GD is a disposable, single-use device, packaged inside a PETG Tray with a Mylar peel cover, which is standard packaging material for medical products.

The Applied Intromit-GD is substantially equivalent to predicate devices in design methodology, principle of operation and clinical utility. The Applied Intromit-GD is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Mr. Anil Bhalani
Director of Regulatory Affairs
and Clinical Programs
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K003871
Trade/Device Name: Applied Intromit-GD
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: March 23, 2001
Received: March 26, 2001

Dear Mr. Bhalani:

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 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). 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 requirements, 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) 594-4659. 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 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/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

Applied Medical Resources is providing this separate cover page for the Intromit-GD "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K003871

Device Name: Applied Intromit-GD

Indications for Use: The Applied Intromit-GD is indicated for use in patients undergoing general laparoscopic surgical procedures to obtain abdominal access by the surgeon's hand while preserving pneumoperitoneum.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *12-12-00*

for Mark N Melkerson

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

510(k) Number K003871

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)