

MAR 13 2006

510(k) SUMMARY

510(k) NUMBER: PENDING

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

CONTACT PERSON: Cheryl Blake
Vice President, Regulatory Affairs and Quality
Systems

DATE OF PREPARATION: January 20, 2006

NAME OF DEVICE: Intuitive Surgical Seal

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery (21CFR
876.1500)

TRADE NAME: Intuitive Surgical Seal

PREDICATE DEVICE: Applied Medical Modular Trocar (K932995)
Applied Medical, Rancho Santa Margarita, CA

INTENDED USE: DESCRIPTION/INDICATIONS:

The Intuitive Surgical Seal is Indicated for use in general, abdominal, gynecological, and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments

DEVICE DESCRIPTION: The Intuitive Surgical Seal is assembled with an Intuitive Surgical cannula and used with a previously approved obturator. The assembly is placed over an incision made through the skin, large enough to accept the tip of the trocar. The trocar assembly is then advanced through the remaining layers of tissue. The obturator is then removed leaving the Intuitive Surgical Seal and Intuitive Cannula in place to allow access to the surgical site for endoscopic instruments while maintaining pneumopertoneum.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Intuitive Surgical Seal included tests to verify the inflation and leakage as compared to its predicate device. The performance and functional testing demonstrated that the Intuitive Surgical Seal is substantially equivalent to its predicate device and it introduces no new safety and effectiveness issues when used as instructed.



MAR 13 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Applied Medical Resources Corporation
c/o Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
455 East Trimble Road
San Jose, California 95131-1230

Re: K060534

Trade/Device Name: Intuitive Surgical Seal
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 27, 2006
Received: February 28, 2006

Dear Mr. Christensen:

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 (240) 276-0120. 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,



Mark N. Melkerson

Mark N. Melkerson
Acting 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 (if known): _____

Device Name: Intuitive Surgical Seal

Indications for Use:

The Intuitive Surgical Seal is Indicated for use in general, abdominal, gynecological, and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes and/or potential spaces for endoscopic instruments

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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