K993544

DEC 22 1999

510(k) SUMMARY
for ADVANCED SURGICAL CONCEPTS
SPACE-OR RETRACTOR

1. SPONSOR

Advanced Surgical Concepts (ASC)
Unit 4, Sunnybank Centre, Bray
County Wicklow
Ireland

Contact Person: Shane MacNally
Telephone: 353 1 2864777

Date Prepared: October 18, 1999

2. DEVICE NAME

Proprietary Name: Space-OR Retractor
Common/Usual Name: Retractor
Classification Name: Manual Surgical Instruments for General Use

3. PREDICATE DEVICES

Lone Star Instruments Retractor System [exempt from 510(k)]
Sklar Surgical Instruments ALM and Meyerding Retractor [exempt from 510(k)]

4. DEVICE DESCRIPTION

The Space-OR is a flexible retractor which can be formed by the user into the desired shape for retraction of organs or tissues during abdominal surgery. The Space-OR can be left in position for a complete abdominal procedure.

In the relaxed position, the Space-OR is malleable and can be placed along a wound edge or in the abdominal cavity. The device can be shaped around the desired organs forming an optimum retractor. The Space-OR includes a connector for wall vacuum. When vacuum is pulled, the device then solidifies, staying in the position formed by the user. The Space-OR will maintain its shape, retracting the desired organs or areas until the clamp is released.

The vacuum applied to the Space-OR must be greater than 150 mmHg for the device to become solid. Once applied, the evacuation tubing is clamped and the vacuum pump removed. The device may be maintained in place for the duration of the surgery. If desired, the user can release the clamp on the vacuum, reposition the Space-OR and re-apply the vacuum.

5. INTENDED USE

The Space-OR is a flexible internal retractor intended for retraction of organs and tissues during abdominal surgery.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Space-OR Retractor is substantially equivalent to the Sklar Surgical Instruments Meyerding Retractor and the ALM Self Retaining Retractor, and the Lone Star Products Retractor System.

The Space-OR is identical in intended use to the Lone Star and Sklar mechanical retractors in that they are all intended to be positioned over target organs or tissues for retraction during abdominal surgery.

The technological characteristics of the Space-OR are similar to the substantially equivalent devices. They are all designed to be positioned over the target area in the abdominal cavity and function as a retractor to hold back organs and/or tissues from the operative area. Metal is used in the substantially equivalent devices whereas the proposed Space-OR is made of PVC. This difference does not adversely affect safety or effectiveness since the PVC has been subjected to and has passed biocompatibility testing. Additionally, the Space-OR has been tested in pigs and has been used clinically in Europe for several years with no adverse effects or complications.

7. PERFORMANCE TESTING

The patient-contacting materials used in the Space-OR have been subjected to and passed biocompatibility testing according to ISO-10993. Animal testing has been performed showing that the Space-OR functions as intended. Additionally, the Space-OR has been in commercial distribution in Europe for over nine years with no complications or adverse effects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1999

Advanced Surgical Concepts
c/o Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K993544
Trade Name: Advanced Surgical Concepts Space-OR Retractor
Regulatory Class: I
Product Code: FFO
Dated: October 18, 1999
Received: October 19, 1999

Dear Ms. McNamara-Cullinane:

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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993544

510(k) Number (if known): K993544

Device Name: Advanced Surgical Concepts Space-OR Retractor

Indications for Use:

The Space-OR Retractor is a flexible internal retractor intended for the retraction of organs and tissues during abdominal surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993544

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

(Optional Format 1-2-96)