K041131

MAY 1 3 2004

510(k) Summary

Sponsor	John C. Pulford Apple Medical Corporation 28 Lord Road, Unit 135 Marlboro, MA 01752	
Date of summary	April 7, 2004	
Device Trade Name	Apple Medical OB Mobius Elastic Retractor	
Common Name	Abdominal Retractor	
Classification Name	Surgical Drape 21 CFR §878.4370 ProCode KKX	Endoscope and Accessories 21 CFR §876.1500, ProCode GCJ
Predicate Devices	Alexis™ Wound Retractor K031889	Mobius Elastic Retractor K014005
Description	The Apple Medical OB Mobius Elastic Retractor is used for laparotomy procedures where a transverse suprapubic incision is made in the abdominal wall allowing access to the peritoneal cavity. Once the incision is made, the internal o-ring is manually collapsed and inserted through the abdominal incision where it is allowed to spring open against the parietal peritoneum. The external quad-ring is then pulled upward placing the cylindrical sleeve in tension and the operator rolls the ring down the sleeve until the ring sits firmly against the skin. The radial force of the two rings act to retract the abdominal wall to the desired circular geometry.	
Intended Use	The Apple Medical OB Mobius Elastic Retractor is indicated for use to assist in laparotomy procedures. It is intended to provide incision retraction and to protect against wound contamination during open surgery.	
Technological Characteristics	The subject device has the same technological characteristics as the predicate devices. The only changes involve a change to the dimensions and labeling for the OB Mobius device. These changes do not affect the safety and effectiveness of the device.	
Testing	The Apple Medical OB Mobius Elastic Retractor has been shown to be substantially equivalent to the predicate Alexis™ device through mechanical properties testing.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Apple Medical Corporation
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

Re: K041131
Trade/Device Name: Apple Medical OB Mobius Elastic Retractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 28, 2004
Received: April 30, 2004

Dear Mr. Mosenkis:

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 (301) 594-4659. 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,

Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K041131

Device Name: Apple Medical OB Mobius

Indications for Use:

The Apple Medical OB Mobius is indicated for use to assist in laparotomy procedures. It is intended to provide incision retraction and to protect against wound contamination during open surgery.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

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