

APR 26 2005

510(k) Summary

Sponsor	Apple Medical Corporation 28 Lord Road, Unit 135 Marlboro, MA 01752
Date of summary	April 20, 2005
Device Trade Name	Apple Medical OB/Mobius® Elastic Retractor (OB/MER)
Common Name	Abdominal Retractor
Classification Name	Obstetric-gynecologic general manual instrument (884.4520) Manual surgical instruments for general use (878.4800) Obstetric-gynecologic specialized manual instrument (884.4530)
Predicate Devices	The Apple Medical OB/Mobius® Elastic Retractor (K041131) and 510(k) exempt mechanical abdominal retractors used in cesarean section.
Description	The Apple Medical OB/Mobius® Elastic Retractor is a sterile disposable abdominal retractor consisting of two flexible plastic rings connected by a sleeve of soft, high yield strength, clear plastic film. The internal ring has a circular cross-section (o-ring) and the external ring has a cruciform cross-section (quad-ring). The inner diameter of the internal o-ring limits the radius of abdominal retraction. The diameter of the external quad-ring is the same as the diameter of the internal o-ring and the sleeve. When completely unwound, the height of the cylinder is 10.6 inches. When the quad ring is rolled down, the sleeve is wrapped around the circumference of the ring reducing the height of the sleeve by 1.5 inches per rotation. Because the sleeve film is radially unyielding, the reduction in height causes the radial retraction of the incision site.
Intended Use	The Apple Medical OB/Mobius Elastic Retractor is indicated for use to assist in non-urgent cesarean deliveries that are routine procedures. It is intended to provide incision retraction and to protect against wound contamination during a cesarean section. It is indicated for use as a surgical retractor for both vertical and transverse incisions.
Technological Characteristics	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 acts to retract the abdominal wall to the desired circular geometry.
Testing	The Apple Medical OB/Mobius Elastic Retractor has been clinically evaluated for the cesarean section indication and shown to be substantially equivalent to the predicate mechanical abdominal retractors.



APR 26 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Apple Medical Corporation
c/o Mr. James Delaney
Boston Healthcare Associates, Inc.
75 Federal St., 9th Floor
BOSTON MA 02110

Re: K050256
Trade/Device Name: Apple Medical OB/Mobius[®] Elastic Retractor
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Product Code: KNA
Regulation Number: 21 CFR §878.4800
Regulation Name: Manual surgical instrument for general use
Product Code: GAD
Regulatory Class: II
Dated: April 1, 2005
Received: April 4, 2005

Dear Mr. Delaney:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050256

Device Name: Apple Medical OB/Mobius® Elastic Retractor

Indications for Use:

The Apple Medical OB/Mobius Elastic Retractor is indicated for use to assist in non-urgent cesarean deliveries that are routine procedures. It is intended to provide incision retraction and to protect against wound contamination during a cesarean section. It is indicated for use as a surgical retractor for both vertical and transverse incisions.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Burdick
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050256

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