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510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Apple Medical Corp. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Apple Medical chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	Apple Medical Mobius Elastic Retractor	
Owner/Operator: (Submitter)	Apple Medical Corporation 28 Lord Road, Unit 135 Marlboro, MA 01752 Registration # 1221923	Contact: John Pulford Phone: (508) 357-2700 Fax: (508) 624-4645
Manufacturer/ Sterilization Site:	GeoTec, Inc. 2800 Post Road, Unit 3 Warwick, RI 02886 Professional Contract Sterilization 40 Myles Standish Boulevard Taunton, Massachusetts 02780	
Device Generic Name:	Abdominal Retractor	
Classification:	According to Section 513 of the Federal Food, Drug , and Cosmetic Act, the device classification is Class II, Performance Standards (21 CFR 878.4370).	
Predicate Device:	Protractor Retractor Marketed by: Dexterity Surgical, Inc. 1495 Hembree Rd., Suite 700 Rosewell, GA 30076 K954824	

Product Description:
The Apple retractor is used for minilaparotomy 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 (ref. Directions for Use). The radial force of the two rings place the sleeve material in tension and the sleeve now acts to retract the abdominal wall to the desired circular geometry. Both the proposed Apple device and the predicate Dexterity device function in an identical way to retract the abdomen. The difference in the two devices is in the ergonomical efficiency of deploying the two devices. The external quad-ring of the proposed Apple device was engineered to have more points around the 360 degree circumference for increased tactile manipulation ability (the predicate has two points in an "oblate spheroid" type of cross-section and the Apple device has four points in a truncated astroid, or "cruciform", cross-section). Further, the Apple device's external quad-ring is formed into a mobius strip during fabrication thus imparting a preset outward torque on the device. This "mobius" type of fabrication coupled with the four points for

tactile feel, results in an external quad-ring which is easier to manipulate into the desired position than is the predicate device while still possessing an equivalent resistance to rollback as the predicate.

Indications for Use:
The Apple Medical Mobius Elastic Retractor is an abdominal retractor used to assist in minilaparotomy procedures. It is intended to provide incision retraction and to protect against wound contamination during open surgery.

Performance Testing:
Substantial equivalence for the proposed Apple Medical Mobius Elastic Retractor is based on a comparison of materials, design, specifications and principle of operation as compared to the predicate device. It has also been shown to be substantially equivalent or superior to the predicate through bench testing, survey and animal studies.

Both the proposed Apple devices and the predicate Dexterity device were bench tested for equivalence by Intertek Testing Services (ITS). ITS independently found that the Apple device was easier to operate as intended than the predicate and that there was no significant difference in either one of the devices resistance to rollback (please see Section 4).

Both the proposed Apple device and the predicate Dexterity device were comparison tested for operability by Dr. Marco Pelosi at DaVinci Biomedical using the porcine model. Dr. Pelosi independently found that the Apple device was easier to operate as intended than the predicate and that there was no significant difference in either one of the devices resistance to rollback (please see section 4).

Conclusion:
Based on the indications for use and technological/design characteristics, the Apple Medical Mobius Elastic Retractor device has been shown to be safe and effective for it intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2002

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

Re: K014005
Trade/Device Name: Apple Medical Mobius Elastic Retractor
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 30, 2002
Received: January 31, 2002

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number (if known): K014005

Device Name: Apple Medical Mobius Elastic Retractor

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

Miriam C Provost

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

510(k) Number K014005