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Appendix VII: 510(k) Summary of Safety and Effectiveness

ClipLoc Soft Tissue Marker

Company:
MRI Devices Corporation
1515 Paramount Drive
Waukesha, WI 53186

Contact:
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Date Prepared:
15 October 2003

Name of Device
Trade Name: ClipLoc Soft Tissue Marker
Classification Name: Implantable Staple

Predicate Devices
Biopsys Medical, Inc (BMI) MicroMark™ Clip (K970817)
Inrad, Inc UltraClip Tissue Marker (K993785)
Ethicon Endo-Surgery, Inc MicroMark II™ Tissue Marker (K013413)
Ethicon Endo-Surgery, Inc 8 Gauge MicroMark II™ Tissue Marker (K020276)
Sanarus Medical, Inc Sanarus Indica Marker System (K020054)
Vivant Medical, Inc VMI Biopsy Marker System (K000278)

Device Description
The ClipLoc Soft Tissue Marker is a sterile, single patient use device comprised of a small nickel-titanium marker (clip), a well as a disposable introducer and applier. The introducer is a coaxial cannula with a beveled tip and a molded hub. The ClipLoc is preloaded near the distal end of the cannula. The applier is a stylette with a cap. A plastic safety connector holds the applier and introducer needle in the appropriate position ("Ready") and helps prevent premature deployment of the marker. After removal of the safety connector, the ClipLoc is deployed by manually advancing the needle.

The ClipLoc may be used with either visual or imaging guidance (such as ultrasound, X-Ray, stereotaxy, or Magnetic Resonance). It may be used directly, or applied through another coaxial needle or guide associated with percutaneous biopsy. The entire system including ClipLoc, introducer, and applier is Magnetic Resonance (MR) safe and compatible up to and including 1.5 Tesla magnetic field strength. The marker, when present in a patient undergoing an MR exam at 3.0 Tesla or less, will not create additional hazard or risk with respect to magnetic field-related interactions, movement, gradient stimulation or heating.

Intended Use
The ClipLoc Soft Tissue Marker is indicated for use to radiographically and radiologically mark the surgical location in breast or other soft tissue following an open or percutaneous procedure.

The ClipLoc® Soft Tissue Marker is intended to attach to soft tissue, including breast tissue, at the surgical site during an open or percutaneous procedure.

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Technological Characteristics
The ClipLoc® Soft Tissue Marker is made of implant grade materials and has similar technological characteristics as the predicate devices. The proposed and predicate devices contain the same primary components to achieve these functions: a handheld applier with deployment mechanism, and a marking clip located at the distal end of the applier. A single marker is deployed through the handheld applier by a push rod. A plastic safety connector holds the applier and introducer needle in the appropriate position ("Ready") and helps prevent premature deployment of the marker. The patient contact components and component materials for positioning the tissue marker in both the new and predicate devices are equivalent. The packaging materials, packaging configuration, sterilization methods and sterility assurance level are also equivalent.

Performance Data
Preclinical testing was performed to confirm the device performs as intended. Satisfactory radiographic visualization of the deployed ClipLoc was achieved using X-Ray, Ultrasound, and Magnetic Resonance (up to and including 3.0 Tesla). The device performs as indicated in magnetic fields up to and including 1.5 Tesla. The ClipLoc Marker is MR safe and compatible up to and including 3.0 Tesla magnetic field strength.

Based on the indications for use, the materials used, as well as the technological characteristics and preclinical testing results, the ClipLoc Soft Tissue Marker does not raise significant new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2004

Mr. Thomas Schubert
President, CEO
MRI Devices Corporation
1515 Paramount Drive
Waukesha, Wisconsin 53186

Re: K033447
Trade/Device Name: ClipLoc Soft Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Radiographic implantable marker
Regulatory Class: II
Product Code: NEU
Dated: October 15, 2004
Received: November 10, 2003

Dear Mr. Schubert:

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): K033447

Device Name: ClipLoc Soft Tissue Marker

Indications For Use:

The ClipLoc™ Soft Tissue Marker is indicated for use to radiographically and radiologically mark the surgical location in breast or other soft tissue following an open or percutaneous procedure.

It is intended to attach to soft tissue, including breast tissue, at the surgical site during an open or percutaneous procedure.

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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033447