FERGUSON MEDICAL

916-342-4133
FAX: 916-343-4541

K962615

MAR 19 1998

15 May 1996

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

A. Classification name: Needle, tumor localization, or guide, surgical, needle, or other.

Common/usual name: Tumor localizer, lesion marker, and others.

Proprietary name: TumorLocalizer MRI

B. Substantial equivalence: Manan Breast Tumor Localization Needle (K863848), Simon Breast Lesion Localization Needle (K914941), MD Tech Kopan Target (K915417), E-Z-Em PercuGuide I (K863090), E-Z-Em PercuGuide Lesion Marking device (K920816), and others.

C. Device description: The TumorLocalizer MRI is a standard needle and hookwire device used for the localization of non-palpable lesions.

D. Intended Use: The device is intended for use to mark or identify by standard radiologic techniques (X-Ray, fluoroscopy, CT, MRI) the location of a soft tissue abnormality such as a cyst, lesion, or tumor.

3407 Bay Avenue • Chico, California 95973 • USA

E. Technological characteristics: The TumorLocalizer MRI is similar to predicate devices in its design, function, and intended use.

The proposed device is different than some tumor localizers in its wire configuration, sizes and gauges of the wire and needle, and shape and operation of the handpiece.

Submitted,
FERGUSON MEDICAL
FDA Establishment Registration Number 2937794

Frank Ferguson
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1998

Mr. Frank Ferguson
Ferguson Medical
3407 Bay Avenue
Chico, California 95973

Re: K962615
Trade Name: TumorLocalizer MRI
Regulatory Class: II
Product Code: MIG
Dated: December 26, 1997
Received: January 5, 1998

Dear Mr. Ferguson:

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,

Stephen Rhodes

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K962615

Device Name: TumorLocalizer MRI

Indications For Use:

The device is intended for use to mark or identify, by standard radiologic techniques (X-Ray, fluoroscopy, CT, MRI) the location of a soft tissue abnormality such as a cyst, lesion, or tumor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K962615

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)