SEP 2 1998

K982157

Attachment 1

510(k) Summary of Safety and Effectiveness

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1.0 SUBMITTER INFORMATION:

1.1 Submitter: Field Effects, a division of Intermagnetics General Corporation
300 Vesper Executive Park
Tyngsborough, MA 01879
PH: **978** 649-8590
FX: **978** 649-8520
Email: GHURST@IGC.com

1.2 Contact: Greg Hurst, Ph.D.
Mgr., Imaging Science and Applications

1.3 Date: June 10, 1998

1.4 Regulatory Counsel:
Jonathan S. Kahan, Attorney at Law
Hogan & Hartson
555 Thirteenth St. NW
Washington, DC 20004-1109
PH: **202** 637-5794
FX: **202** 637-5910

2.0 DEVICE NAME:

2.1	Classification Panel:	Radiology
2.2	Classification Number:	892.1000 Magnetic Resonance Diagnostic Device
2.3	Product Nomenclature:	System, Nuclear Magnetic Resonance Imaging
2.4	Product Code(s):	90LNH 90MOS (Magnetic Resonance Specialty Coil)
2.5	Trade/Proprietary Name:	TREX MRI
2.6	Predicate Device:	IMiG-MRI

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

Identical to the IMiG-MRI 510(k) K963953. As a result of newly created business arrangements, the original IMiG-MRI system will now be renamed as TREX MRI. With the exception of the device modifications identified in this 510(k) submission, and the renaming of the product, the TREX MRI is identical to the original IMiG-MRI system.

The TREX MRI 0.15T Elliptical MRI Magnetic Resonance Diagnostic Device is being enhanced by three additional RF Coils (Head Coil [quadrature], C-Spine Coil [quadrature], and Knee Coil [linear]) to increase the clinical utility of the TREX MRI in the stationary configuration.

The new quadrature Head Coil (Field Effects P/N 96530-01) will have a smaller diameter of 19 cm. The reduction in diameter will allow for improved coil fill factor, increasing SNR, while maintaining optimal coil uniformity. This new coil will replace the original Head Coil.

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The new C-Spine Coil Field Effects P/N 96529-01) is substantially re-designed from the original coil, optimized for Cervical Spine imaging, and reducing the potential for patient anxiety and claustrophobia. This new coil utilizes a proprietary multiple receiver coil design, and will replace the original C-Spine/Knee Special Purpose Coil.

The new Knee Coil (Field Effects P/N 96629-01) utilizes a proprietary solenoid receiver coil design optimized for knee and extremity anatomies, improving coil fill factor, and increased S/N Ratio.

TREX MRI software did not need to be revised in order to support full functionality of these coils.

3.2 Safety Parameter Summary

Maximum static magnetic field	0.15 Tesla
Maximum rate of magnetic field change	18.4 Tesla/sec
Maximum RF power deposition	0.05W/kg
Acoustic noise levels	114dB peak; 95dB A-weighted RMS

3.3 Performance Parameter Summary

Receiver Coil	**Head**	**Body**
Specification Volume	15cm dsv	30cm dsv
SNR	> 34.2	>33.1
Uniformity	< 14 %	<40%
Geometric Distortion	< 2.5%	<3.5%
Slice Thickness	within 10% of nominally designated value	
Slice Position	within 10% of nominally designated value	
Spatial resolution	nominally equivalent to pixel size	

3.4 General Safety and Effectiveness Summary

Safe and effective use of the machine is assured by associated labeling. This labeling includes: advertising brochures, Site Planning Guide, and Instructions for Use (comprised of Clinical Users Guide, User Safety Guide, User Training Guide, User Applications Guide, and User QA & Maintenance Guide).

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4.0 DEVICE INTENDED USE:

The TREX MRI system produces cross-sectional images:

- Anatomical Region: General body anatomy, including head, spine, torso, and extremities
- Nucleus excited: 1H nuclei (Proton)
- Diagnostic uses: Images correspond to the distribution of 1H nuclei exhibiting nuclear magnetic resonance, with image intensity dependent upon NMR parameters, including
  spin-lattice relaxation time (T1)
  spin-spin relaxation time (T2)
  density of nuclei (ρ)
  flow velocity
  chemical shift (δ)
- Clinical use: Images may be interpreted by a trained physician to yield information that can be useful in the determination of a diagnosis

5.0 DEVICE TECHNOLOGICAL CHARACTERISTICS:

Identical to the Predicate Device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1998

Greg Hurst, Ph.D.
Mgr., Imaging Science and Applications
Field Effects, A Division of Intermagnetics General Corp.
300 Vesper Executive Park
Tyngsborough, Massachusetts 01879

Re: K982157
TREX Magnetic Resonance Diagnostic Device
Dated: June 10, 1998
Received: June 19, 1998
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Dr. Hurst:

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982157

Device Name: TREX MRI MAGNETIC RESONANCE DIAGNOSTIC DEVICE + SUPPLEMENTAL RF COILS

Indications for Use:

The TREX MRI system produces cross-sectional images:

- Anatomical Region: General body anatomy, including head, spine, torso, and extremities
- Nucleus excited: 1H nuclei (Proton)
- Diagnostic uses: Images correspond to the distribution of 1H nuclei exhibiting nuclear magnetic resonance, with image intensity dependent upon NMR parameters, including
  - spin-lattice relaxation time (T1)
  - spin-spin relaxation time (T2)
  - density of nuclei (ρ)
  - flow velocity
  - chemical shift (δ)
- Clinical use: Images may be interpreted by a trained physician to yield information that can be useful in the determination of a diagnosis.
- RF Coils: Head - quadrature
  Cervical Spine - quadrature
  Lumbar Spine, Thoracic Spine, and Abdomen - quadrature
  Knee - linear
- Image Acquisition Spin Echo
  Gradient Echo (GE,RGE)
  Fast Spin Echo (FSE)
  Fast Dual Echo (FDE)
  3D Fast Gradient Echo (3DGE, 3DRGE)
  Inversion Recovery with Fast Spin Echo (FSE STIR, FSE FLAIR)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982157

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801-109

(Optional Format 1-2-96)
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