

K 990968

MAY 27 1999

510(k) Summary  
E-Scan  
Biosound Esaote

### 510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR§807.92(a).

807.92(a)(1)

#### Submitter Information

Colleen Hittle, Official Correspondent  
8000 Castleway Drive  
Indianapolis, IN 46250  
Phone: (317) 849-1916  
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: March 10, 1999

807.92(a)(2)

Trade Name: E-Scan

Common Name: Magnetic resonance diagnostic device

Classification Name(s): System, Nuclear Magnetic Resonance Imaging

Classification Number: ~~SECRET~~

807.92(a)(3)

#### Predicate Device(s)

Esaote                                      Artoscan S                                      K981358

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

RA  
IT

510(k) Summary  
E-Scan  
Biosound Esaote

807.92(a)(5)

### **Intended Use(s)**

The E-Scan is intended for diagnostic nuclear magnetic resonance imaging of the hip, leg, knee, ankle, foot, shoulder, elbow, forearm, wrist and hand. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

The system preliminarily named "Artoscan S" is going to be commercialized under the trade name "E-Scan". The changes performed, with respect to the cleared version, are due to the optimization process of the system, in particular in relation to an improvement of the accessibility inside the gantry and therefore toward a greater patient comfort. The intended use of the modified device has not changed as a result of the modifications nor such modifications alter its fundamental scientific technology.

510(k) Summary  
 E-Scan  
 Biosound Esaote

**Comparison Chart for Substantial Equivalence**

Item	Artoscan S	E-SCAN	Comments
# slices per echo	1 – 128	1 – 96	
Homogeneity	< ± 30 ppm on 120 mm DSV	< ± 50 ppm (pk pk) on 140 mm DSV	Final result allows to enlarge the Field of View
Fringe field (0,5 mT line)	0,5 mT line: 140 cm from the center of the magnet  X axis: 140 cm front; 90 cm rear; Y axis: 120 cm right/left; Z axis: 90 cm top/bottom	0,5 mT line: 150 cm from the center of the magnet  X axis: 150 cm front, 120 rear; Y axis: 130 cm right/left Z axis: 150 cm top/bottom	Variations due to the industrialization of the magnet
RF Shielding	Self contained RF shielding (up to 30 dB $\mu$ V/m)  External shielding (up to 100 dB $\mu$ V/m)	Integrated RF shielding (up to 30 dB $\mu$ V/m)  Shielding Box (up to 60 dB $\mu$ V/m)  External shielding (up to 100 dB $\mu$ V/m)	The term "integrated" represents better the concept than "self-contained"  A shielding box has been added as intermediate solution, in terms of both performances and costs, between the integrated RF shielding and the traditional RF cage (as this latter is always possible but more expensive).
Gradients' rise time	0.5 ms from 0 to 20 mT or from -20 to 0 mT	0.8 ms from 0 to 20 mT/m from 0 to 99%	More precise characterization of the data
Sequences		The sequence preliminary indicated as GEFS has been renamed into GE-STIR	

510(k) Summary  
 E-Scan  
 Biosound Esaote

**Comparison Chart for Substantial Equivalence**  
**Continued**

<b>Item</b>	<b>Artoscan S</b>	<b>E-SCAN</b>	<b>Comments</b>
Anatomical regions	Limbs: in particular Hip, Knee, Leg, Ankle, Foot, Hand, Wrist, Forearm, Elbow and Shoulder	Limbs: in particular Hip, Knee, Leg, Ankle, Foot, Hand, Wrist, Forearm, Elbow, Arm and Shoulder	It was possible to examine arms also before but it was necessary to select <b>Other</b> and to introduce the Arm data. Now arm is included in the <b>standard</b> and most common districts to be examined with E-scan
Installation area	3.7 x 3.7 sq. m.	Integrated shielding: 3.7 x 4 mt  Shielding box: 4 x 4.5 sq. m. (min height 2.4 m)	Variation due to the industrialization of the system.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 27 1999

Colleen Hittle  
Official Correspondent  
Biosound Esaote, Inc.  
8000 Castleway Drive  
Indianapolis, Indiana 46250

RE: K990968  
E-Scan Magnetic Resonance Diagnostic Device  
Dated: March 19, 1999  
Received: March 23, 1999  
Regulatory Class: II  
21 CFR 892.1000/Procode: 90 LNH

Dear Ms. Hittle:

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 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). 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications For Use**

510(k) Number (if known): K 990968

Device Name: E-Scan

**Indications for Use:**

The E-Scan is intended for diagnostic nuclear magnetic resonance imaging of the hip, leg, knee, ankle, foot, shoulder, elbow, forearm, wrist and hand. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

The system preliminarily named "Artoscan S" is going to be commercialized under the trade name "E-Scan". The changes performed, with respect to the cleared version, are due to the optimization process of the system, in particular in relation to an improvement of the accessibility inside the gantry and therefore toward a greater patient comfort. The intended use of the modified device has not changed as a result of the modifications nor such modifications alter its fundamental scientific technology.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-The-Counter Use

David W. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990968