510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR §807.92(a).

807.92(a)(1)

Submitter Information

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

Contact Person: Carri Graham
Date: April 30, 2004

807.92(a)(2)

Trade Name: E-Scan XQ
Common Name: Magnetic resonance diagnostic device
Classification Name(s): System, Nuclear Magnetic Resonance Imaging
Classification Number: 90LNH

807.92(a)(3)

Predicate Device(s)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device Type</th>
<th>Classification Number</th>
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<tbody>
<tr>
<td>Esaote</td>
<td>E-Scan</td>
<td>K990968</td>
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<tr>
<td>Esaote</td>
<td>E-Scan</td>
<td>K001894</td>
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<tr>
<td>Esaote</td>
<td>Hip Coil</td>
<td>K012728</td>
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<td>Esaote</td>
<td>E-Scan XQ</td>
<td>K020164</td>
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<tr>
<td>Esaote</td>
<td>E-Scan XQ</td>
<td>K032121</td>
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Device Description

The DPA Shoulder Coil is to be used with the E-scan XQ magnetic resonance imaging system. It is a receiving coil designed to be "worn" by the patient and is the result of the combination of two different coils. The first is the primary coil and is composed of 4 turns connected in a series with 4 tuning capacitors positioned under the patient's armpit. The second surface coil consists of 3 turns designed to improve the image homogeneity and having spatially complementary sensitivity with respect to the primary coil. The coil allows for imaging of both the left and right shoulder, due to the symmetrical mechanical connection between its base and the magnet.

Intended Use(s)

E-scan XQ is a magnetic resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It is intended for imaging the upper limb, including the hand, wrist, forearm, elbow, upper arm and shoulder, and imaging the lower limb, including the foot, ankle, calf, knee, thigh and hip.

E-scan XQ MR images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin–lattice relaxation time (T1), spin–spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.
## Technological Characteristics

**Comparison to the cleared device**  
E-scan XQ K032121

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>E-scan XQ K032121</th>
<th>Modified E-scan XQ</th>
<th>Comments</th>
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| DPA receiving coils              | 2 Knee coil: 22.5 x 21.0 x 18.3 cm (h x w x d) external; 14.3 x 16.0 x 18.3 cm (h x w x d) internal  
3 Hand coil: 17.8 x 17.5 x 20 cm (h x w x d) external; 11.9 x 7.2 x 20 cm (h x w x d) internal  
4 Foot/Ankle coil: 22.0 x 19.2 x 28.5 cm (h x w x d) external; 14.6 x 10.0 x 28.5 cm (h x w x d) internal | 2 Knee coil: 22.5 x 21.0 x 18.3 cm (h x w x d) external; 14.3 x 16.0 x 18.3 cm (h x w x d) internal  
3 Hand coil: 17.8 x 17.5 x 20 cm (h x w x d) external; 11.9 x 7.2 x 20 cm (h x w x d) internal  
4 Foot/Ankle coil: 22.0 x 19.2 x 28.5 cm (h x w x d) external; 14.6 x 10.0 x 28.5 cm (h x w x d) internal  
7 Shoulder coil: 25.5 x 18.5 cm (larger opening)  
13.3 x 13.3 cm (smaller opening) | The technological characteristics of the DPA 7 Shoulder coil are similar to the characteristics of the predicate device DPA receiving coils.  
The coil is designed to be morphologically adapted to the examined area for increasing the Signal-to-Noise Ratio.  
See section “DPA Shoulder Coil Description”.
Dear Ms. Graham:

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 one of the following numbers, based on the regulation number at the top of the letter:

- 8xx.1xxx (301) 594-4591
- 876.2xxx, 3xxx, 4xxx, 5xxx (301) 594-4616
- 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx (301) 594-4616
- 892.2xxx, 3xxx, 4xxx, 5xxx (301) 594-4654
- Other (301) 594-4692

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) you may obtain. 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,

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): \(K041145\)

Device Name: E-scan XQ MR System.

Indications for Use:

E-scan XQ is a magnetic resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, and imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip.

E-scan XQ MR images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin–lattice relaxation time \((T_1)\), spin–spin relaxation time \((T_2)\), nuclei density, flow velocity and “chemical shift”. When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.