



K954353
GE Medical Systems

0.2T EXTREMITY COIL

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0.2T Extremity Coil

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General Electric Medical Systems

SUMMARY OF INFORMATION REGARDING SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

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Product: 0.2T Extremity Coil
Manufactured by GE Yokogawa Medical System, Ltd.
Tokyo, Japan

1) Indications for Use

The 0.2T Extremity Coil expands the capability of the 0.2T MR imaging system. It accommodates and improves imaging of the knee and surrounding structures. It can also be used to image other extremity body parts such as the ankle and wrist.

2) Device Description

The 0.2T Extremity coil is a quadrature receive-only coil contained in a biocompatible outer shell. The coil comes with an adjustable positioning base and patient comfort pads for support. It is designed specifically for use with a vertical magnetic field MR imaging system.

3) Marketing History


The 0.2T Extremity Coil has not been previously marketed by GE Medical Systems.

4) Potential Adverse Effects on Health

The use of the 0.2T Extremity Coil does not result in any additional potential hazards compared to previously marketed receive-only surface coils.

5) Conclusions

It is the opinion of GE Medical Systems that the 0.2T Extremity Coil is substantially equivalent to the presently marketed GE MR Max Plus Extremity Coil (#K895794).


10/10/95
L. A. Kroger