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GE Medical Systems

General Electric Company
P. O. Box 414, Milwaukee, WI 53201

K964306

Signa SP Flex Coils

October 28, 1996

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: Signa SP Flex Coils
Manufactured by General Electric Medical Systems
Waukesha, Wisconsin, USA**

1) Indications for Use

The Signa SP Flexible Coil family provides imaging capability for the Signa SP MR System by facilitating magnetic resonance imaging of irregular anatomy and providing a mechanism for static or dynamic (i.e., flexion of joints or the spine) dynamic magnetic resonance imaging.

2) Device Description

The Signa SP Flex Coils are a group of symmetric transmit/receive surface coils of varying dimensions that are coupled as helmholtz pairs and contained in a flexible, biocompatible outer covering.

3) Marketing History

The Signa SP Flex Coils have not been previously marketed by GE Medical Systems.

4) Potential Adverse Effects on Health

The use of the Signa SP Flex Coils does not result in any additional potential hazards compared to previously marketed flexible transmit/receive surface coils.

5) Conclusions

It is the opinion of GE Medical Systems that the Signa SP Flex Coils are substantially equivalent to the presently marketed transmit/receive flexible surface coil contained in the Signa SP MR System (K942604).