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510(K) SUMMARY
(as required by 807.92(c))

K964141

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
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Date of Summary: October 4, 1996

Trade Name: GE Sterile Disposable Equipment Coil Cover

Classification Name: Sterile Disposable Equipment Cover

Predicate Device: Contour Fabricators Inc. Bandbag, Wrap, Sterile,
Disposable Fluoroscope and General Equipment
Cover. K782155

Device Description/ An MRI system requires the use of a remote transmitting coil to generate the localized images. The coil is placed on the area of the patient where the operating incision is made. The coil itself resembles a window frame.

These coils are very susceptible to damage caused by various fluids that may be release during an invasive procedure. To protect these coils, a Sterile Disposable Equipment Cover is used to seal the coil inside a wrapper preventing it from fluid contamination. The Sterile Disposable Equipment Cover is made from PVC Film and the strap is polynap of 100% nylon fabric with polyester foam core and nylon tricot backing.

Comparison:

Materials	Contour Fabricators	Contour Fabricators K782155
Cover	PVC Film	Polyethylene
Strap	Foam	Rubber Band
Packaging	Tyvek/Mylar Pouch	Tyvek/Mylar Pouch
Sterilization	ETO	ETO

Intended Use: The GE Sterile Disposable Equipment Cover is intended to protect equipment from fluids. Specifically, a coil used in the GE Magnetic Resonance Imaging (MRI) System.