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RE: 510(k) Notification: Medtronic Model 3550 Accessories

In order to comply with the Safe Medical Devices Act of 1990, this one page will provide safety and effectiveness information to interested persons.

SUMMARY OF SAFETY AND EFFECTIVENESS

Medtronic considers nonsterile packaging of spinal cord and peripheral nerve stimulation lead accessories with appropriate labeling and instructions for sterilization by the user to be substantially equivalent in design, function, materials, and intended use to previous accessory devices. Packaging of the nonsterile accessories will be either in kits, as separate piece parts or in bulk packaging that in no way resembles sterile packaging. The word "Nonsterile " will be obviously displayed on the packaging and instructions for sterilization will be included in the labeling.

Sincerely,

MEDTRONIC, INC.
Neurological Business

Jean Prather
Senior Clinical Research Associate