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**RE: 510(k) Notification: Medtronic Model 3628 Screener**

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

SUMMARY OF SAFETY AND EFFECTIVENESS

The Medtronic Model 3628 Screener is indicated for use in trial screening for SCS and PNS for chronic intractable pain of the trunk or limbs, as is the Model 3627 Screener and the Model 3210 Transmitter. The Model 3628 Screener is a combination of the Model 3627 Screener and the Model 3210 Transmitter. Electrically and functionally, it is the same as the two current products combined. The new Screener allows the patient to carry one unit rather than two during the screening period.

There are only minor differences between the Model 3628 Screener and the commercially available Model 3627/3210 units, which are as follows:

1. A larger liquid crystal display (LCD); used to display parameter information.
2. The antenna and receiver coil in the current products have been replaced with a RF transformer.
3. Several items (pushbuttons, switches, etc.) have been relocated for improved ease of use.

Therefore, the Model 3628 Screener is substantially equivalent to current Model 3627/3210 units.

Sincerely,

MEDTRONIC, INC.  
Neurological Division

Dennis H. Crane  
Principal Regulation Manager