K953742

510(k) SUMMARY
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A. Submitter Information

Submitter's Name:	Medtronic, Inc.
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B. Device Information

Trade Name:	Medtronic Model 7498 Bifurcated Y-extension; Medtronic Bifurcated Y-screening cable
Common Name:	Permanent Bifurcated Y-Extension; Temporary Y-Screening Cable
Classification Name:	Class II spinal cord stimulation devices (21 CFR 882.5880)
Predicate Device:	This 510(k) summary identifies the Model 7495 extension as substantially equivalent to the proposed Model 7498 bifurcated y-extensions. The y-extension is also substantially equivalent to the previously approved Model 3470 receiver extensions when two receivers are implanted together with two leads and two extensions. Additionally, the two side by side leads resulting from use of a y-extension are equivalent to the following leads which use horizontally side by side electrodes in a single channel or a single power

source system: the Model 3983, the Model 3982 and the Model 3991. The current screening cable for use with the Model 3625 is substantially equivalent to the proposed bifurcated y- screening cable.

Device Description: The proposed y-extension and screening cables are identical to previously approved extensions and screening cables except for the addition of a second in-line, set screw connector. The dual connectors are parallel to each other and are attached proximally in the IPG plug (extension) or at a y-junction (screening cable). The distal and proximal ends of the proposed and current extension and screening cables are identical and the only difference is the connection at the IPG plug (extension) and at the y-junction (screening cable).

Intended Use: The intended use of the bifurcated y-extension is Spinal Cord Stimulation to treat chronic intractable pain.

C. Comparison of Required Technological Characteristics

The y-extensions are substantially equivalent to the commercially-approved Model 7495 extension. The y-extension differs only in that it allows for two identical, parallel in-line set screw connectors. Testing showed that the y-extension does not raise any new questions of safety and effectiveness.

Except for the additional leg, the EXTENSIONS AND SCREENING CABLES THEMSELVES ARE IDENTICAL TO PREVIOUS COMMERCIALLY RELEASED MODEL 7495 EXTENSIONS AND SCREENING CABLES. The extensions and screening cables are unchanged in other aspects of device design, function, and intended use.

Table 2. Comparison of Required Characteristics

Characteristics	Current and Proposed Y- Extensions (Models 7495YC and 7498)	Current Single-line Extensions and Proposed Y-Extension	Current Screening Cable and the Y-Screening Cable
a. Product Labeling	Substantially equivalent	Substantially equivalent	Substantially equivalent
b. Intended Use	Identical	Identical	Identical
c. Physical Characteristics	Substantially equivalent	Substantially equivalent	Substantially equivalent
d. Anatomical Sites	Identical	Identical	Identical
e. Target Population	Identical	Identical	Identical
f. Performance Testing	Substantially equivalent	Substantially equivalent	Substantially equivalent
g. Safety Characteristics	Substantially equivalent	Substantially equivalent	Substantially equivalent

D. Summary of Nonclinical Tests

Laboratory tests for flex strength and tensile strength showed that the Model 7498 extension passed the requirements. In conclusion, the laboratory results show that the bifurcated y-connector design does not raise any new questions of safety and efficacy and that the y-extensions and y-screening cable are substantially equivalent to the current extensions and screening cables.