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K960446

510(k) SUMMARY

[As required by 21 CFR 807.92(a)]

A. Submitter Information

Submitter's Name: Medtronic, Inc.

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Submission
Preparation Date: January 31, 1996

B. Device Information

Trade Name: Models 5471 and 5471L Sterile Disposable Patient Cable Assemblies

Common Name: Patient Cable

Classification Name: Patient transducer and electrode cable (including connector), Class II (21 CFR 870.2900)

Predicate Device: This 510(k) summary identifies the Models 5455, 5455L, 5455S, and 5455SL surgical cables as substantially equivalent to the proposed patient cable assemblies.

Device Description: The proposed patient cables are identical to the commercially-approved Models 5455, 5455L, 5455S, and 5455SL surgical cables, with the exception of a modified connector for heart wires and leads.

Intended Use: The intended use of the patient cables is identical to previous patient cables.

C. Comparison of Required Technological Characteristics

The proposed patient cables are substantially equivalent to the commercially-available Models 5455, 5455L, 5455S, and 5455SL surgical cables. The proposed cables are identical to the current cables except that the proposed cables include a modified connector.

Characteristics	Current and Proposed
a. Product Labeling	Substantially equivalent
b. Intended Use	Identical
c. Physical Characteristics	Substantially equivalent
d. Anatomical Sites	Identical
e. Target Population	Identical
f. Performance Testing	Substantially equivalent
g. Safety Characteristics	Substantially equivalent

D. Summary of Nonclinical Tests

Mechanical, electrical, and environmental/packaging tests show that the proposed patient cable assemblies are qualified and raised no new questions with regard to safety and efficacy. Mechanical test results for cable retaining force, lead, and heartwire connection withdrawal forces, and button depression all met requirements. Electrical tests for current, resistance, and dielectric withstanding voltage also met requirements. Environmental/packaging tests demonstrated that the packaging can withstand various shock, vibration, temperature, and humidity conditions. Biocompatibility tests showed that the connector does not produce cytotoxicity or dermal irritation. All tests met their respective requirements.