

K233838 Emprint Ablation System with Thermosphere Technology (Overall System Name)

Mar 28, 2024
115 days to decisionK233838 · Product code: **NEY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k233838/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Dec 4, 2023
Decision date	Mar 28, 2024
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Emprint Ablation Generator (CAGEN1); Emprint Ablation Generator HP (CAGENHP); Emprint Ablation Pump (CAPUMP1); Covidien™ Ablation Footswitch (RFASW); Emprint Reinforced Percutaneous Antenna 15cm (CA15L2); Emprint Reinforced Percutaneous Antenna 20cm (CA20L2); Emprint Reinforced Percutaneous Antenna 30cm (CA30L2); Covidien™ Remote Temperature Probe (RTP20); Covidien™ Remote Temperature Probe, Bulk (RTP20B)

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Steve Pavlik
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...