

K233830 OsteoCool™ 2.0 RF Ablation SystemFeb 28, 2024
89 days to decisionK233830 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 1, 2023
Decision date	Feb 28, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Jeff Sprague
510(k) history	170 submissions · 159 cleared · 2000-2026

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