

K182497 OsteoCool RF Ablation SystemJan 15, 2019
125 days to decisionK182497 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 12, 2018
Decision date	Jan 15, 2019
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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