

**K253656 OsteoCool™ RF Ablation System**Jun 5, 2026  
197 days to decisionK253656 · Product code: **GEI** · Orthopedic  
Source: <https://www.510kdatabase.net/k253656/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 20, 2025
Decision date	Jun 5, 2026
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OsteoCool™ 2.0 RF Ablation System

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	Jeff Sprague
510(k) history	171 submissions · 160 cleared · 2000-2026

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