

**K060400 CARDIABLATE SURGICAL ABLATION GENERATOR,
MODEL 68000**Feb 28, 2006
13 days to decisionK060400 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k060400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 15, 2006
Decision date	Feb 28, 2006
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary
Other names	CARDIABLATE BP2 SURGICAL ABLATION DEVICE, MODEL 60831; CARDIABLAT

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	DAVID D COX
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,...

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