

K223508 Cardioblade Gemini-s 49260 Surgical Ablation DeviceDec 22, 2022
30 days to decisionK223508 · Product code: **OCL** · Cardiovascular
Source: <https://www.510kdatabase.net/k223508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Nov 22, 2022
Decision date	Dec 22, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cardioblade Gemini-s 49351 Surgical Ablation Device

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Rajitha Nair
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,...