FDA 510(k) Premarket Notification

CLEARED

K070311 CARDIOBLATE GEMINI SURGICAL ABLATION DEVICE, MODELS 49260 AND 49261

Apr 24, 2007
82 days to decision

K070311 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k070311/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 1, 2007
Decision date	Apr 24, 2007
Days to decision	82 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Vascular**
Location	Walker, MI, US
Contact	DEBBIE KIDDER
510(k) history	475 submissions · 453 cleared · 1977-2023