FDA 510(k) Premarket Notification

K061865 FLEX 10 MIS ABLATION PROBE, MODEL FLX10MI-05

CLEARED

Jul 27, 2006
24 days to decision

K061865 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k061865/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Jul 3, 2006
Decision date	Jul 27, 2006
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	CHRISTINA L LOWE
510(k) history	71 submissions · 56 cleared · 1997-2006

Guidant Corp. is a medical device manufacturer specializing in cardiovascular devices and surgical products. Headquartered in Indianapolis, Indiana, the company designs and manufactures artificial cardiac pacemakers, implantable cardioverter-defibrillators, stents, and related cardiovascular medical products. Guidant received FDA 510(k) clearances from total submissions between 1997 and 2006. The company's regulatory portfolio is dominated by cardiovascular devices, including guide wires, embolic protection systems, stents, and hemostasis valves. The company also cleared ...