FDA 510(k) Premarket Notification

CLEARED

K014250 7MM EXTENDED LENGTH ENDOSCOPE,DISSECTION TIPS, MODELS VH-1111, VH-1114

Jan 10, 2002
15 days to decision

K014250 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k014250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 26, 2001
Decision date	Jan 10, 2002
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	ANNE SCHLAGENHAFT
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 ...