

K023627 ESSEX ENDOSCOPE, MODEL SXD-1000Nov 12, 2002
15 days to decisionK023627 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k023627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Oct 28, 2002
Decision date	Nov 12, 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 ...
