K993639 RX VIATRAC 18 PERIPHERAL DILATATION CATHETER, OTW VIATRAC 18 PERIPHERAL DILATATION CATHETER

CLEARED

Jan 27, 2000
91 days to decision

K993639 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k993639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 28, 1999
Decision date	Jan 27, 2000
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Guidant Corp.**
Location	Santa Clara, CA, US
Contact	SUSAN SILAVIN
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 ...