FDA 510(k) Premarket Notification

CLEARED

K993907 VIRIDIA INFORMATION CENTER SOFTWARE FOR M3154A OPT C22

Dec 6, 1999
19 days to decision

K993907 · Product code: **MHD** · General Hospital
Source: https://www.510kdatabase.net/k993907/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Gallstone Dissolution (MHD)
Date received	Nov 17, 1999
Decision date	Dec 6, 1999
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Agilent Technologies, Inc.**
Location	Pittsburgh, PA, US
Contact	DAVE OSBORN
Website	http://www.agilent.com
510(k) history	30 submissions · 30 cleared · 1985-2017

Agilent Technologies, Inc. is an American global company that provides instruments, software, services, and consumables for laboratories. Headquartered in Santa Clara, California, Agilent was established in 1999 as a spin-off from Hewlett-Packard. The company has received FDA 510(k) clearances from total submissions. Cardiovascular devices represent the dominant focus, accounting for approximately 80% of regulatory submissions. Agilent's FDA 510(k) clearance history spans from 1985 to 2017, establishing a long track record in medical device regulation. Notable cleared dev...