FDA 510(k) Premarket Notification

K023880 CARDIO VATIONS STEERABLE CORONARY SINUS CATHETER

CLEARED

Dec 11, 2002
20 days to decision

K023880 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k023880/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 21, 2002
Decision date	Dec 11, 2002
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	PETER CECCHINI
Website	https://www.jnjmedtech.com
510(k) history	204 submissions · 197 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...