FDA 510(k) Premarket Notification

K963214 CORDIS ST STEERABLE GUIDEWIRE

CLEARED

Nov 13, 1996
89 days to decision

K963214 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k963214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 16, 1996
Decision date	Nov 13, 1996
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	Lisa Wells
Website	https://cordis.com
510(k) history	315 submissions · 281 cleared · 1976-2014

Cordis Corp. is a medical device manufacturer based in McHenry, US. The company specializes in interventional cardiovascular and gastroenterology devices. Cordis has a substantial FDA 510(k) regulatory history spanning from 1976 to 2014. The company received FDA 510(k) clearances from total submissions. Its portfolio focuses primarily on cardiovascular devices and gastroenterology stent systems, including percutaneous transluminal angioplasty catheters, emboli capture guidewires, and self-expanding biliary stent systems. Notable cleared products include the FLEXSTENT Bili...