

K801910 INSULATING SHEATHSep 9, 1980
29 days to decisionK801910 · Product code: **DXY** · Cardiovascular
Source: <https://www.510kdatabase.net/k801910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Aug 11, 1980
Decision date	Sep 9, 1980
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Cordis Corp.
Location	Mchenry, IL, US
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...

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