FDA 510(k) Premarket Notification

K913636 ORBIS-SIGMA VALVE SYSTEM FOR VENTRICULAR SHUNTING

CLEARED

Dec 12, 1991
119 days to decision

K913636 · Product code: **JXG** · Neurology
Source: https://www.510kdatabase.net/k913636/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Aug 15, 1991
Decision date	Dec 12, 1991
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	MARVIN L SUSSMAN
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...