FDA 510(k) Premarket Notification

K843751 CORDIA HS ANTIBODY TYPING REAGENTS

CLEARED

Apr 24, 1985
211 days to decision

K843751 · Product code: **GQN** · Microbiology
Source: https://www.510kdatabase.net/k843751/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN)
Date received	Sep 25, 1984
Decision date	Apr 24, 1985
Days to decision	211 days
Third-party review	No

APPLICANT

Company	**Cordis Corp.**
Location	Mchenry, IL, US
Contact	SEYMOUR P HALBERT
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...