

K053195 SPIDERX EMBOLIC PROTECTION DEVICEJun 23, 2006
220 days to decisionK053195 · Product code: **NFA** · Cardiovascular
Source: <https://www.510kdatabase.net/k053195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection (NFA)
Date received	Nov 15, 2005
Decision date	Jun 23, 2006
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ev3, Inc.
Location	Plymouth, MN, US
Contact	BRENDA JOHNSON
510(k) history	35 submissions · 26 cleared · 2003-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 6, 2026