

K050889 FIBRIN ANALYSIS SYSTEM ENDOLUMINAL BRUSHAug 26, 2005
142 days to decisionK050889 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k050889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Apr 6, 2005
Decision date	Aug 26, 2005
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Crs Medical Diagnostics, Inc.
Location	Pewaukee, WI, US
Contact	JOSEPH M MATTANO
510(k) history	2 submissions · 2 cleared · 2005-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050889/> 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 26, 2026