FDA 510(k) Premarket Notification

# K050889 FIBRIN ANALYSIS SYSTEM ENDOLUMINAL BRUSH

**CLEARED**

Aug 26, 2005
142 days to decision

K050889 · 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 |