

K130135 DANA REUSABLE BI TEST PACKNov 25, 2013
311 days to decisionK130135 · Product code: **JOJ** · General Hospital
Source: <https://www.510kdatabase.net/k130135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Physical/chemical Sterilization Process (JOJ)
Date received	Jan 18, 2013
Decision date	Nov 25, 2013
Days to decision	311 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dana Products, Inc.
Location	South Barrington, IL, US
Contact	HARRY BALA
510(k) history	9 submissions · 9 cleared · 2002-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130135/> 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 7, 2026