FDA 510(k) Premarket Notification

K103321 DANA REUSABLE TESTPACK FOR STEAM STERILIZATION FOR 10 MINUTE EXTENDED CYCLES

CLEARED

Feb 16, 2011
96 days to decision

K103321 · Product code: **FRC** · General Hospital
Source: https://www.510kdatabase.net/k103321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Nov 12, 2010
Decision date	Feb 16, 2011
Days to decision	96 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.net
Device record: https://www.510kdatabase.net/k103321/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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