FDA 510(k) Premarket Notification

K073326 NRG TRANSSEPTAL NEEDLE

CLEARED

May 28, 2008
183 days to decision

K073326 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k073326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	Nov 27, 2007
Decision date	May 28, 2008
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baylis Medical Co., Inc.**
Location	Mississauga, CA
Contact	MEGHAL KHAKHAR
510(k) history	28 submissions · 28 cleared · 1998-2013