FDA 510(k) Premarket Notification

CLEARED

K082075 HANSEN MEDICAL DILATOR FOR ARTISAN CONTROL CATHETER

Aug 15, 2008
23 days to decision

K082075 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k082075/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jul 23, 2008
Decision date	Aug 15, 2008
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hansen Medical, Inc.**
Location	Mountain View, CA, US
Contact	KATE WHITIN
510(k) history	14 submissions · 10 cleared · 2006-2016