FDA 510(k) Premarket Notification

K092896 REMPRESS AND ANGIOGRAPHY CONTRAST DELIVERY SYSTEM REMPRESS

CLEARED

Oct 29, 2010
403 days to decision

K092896 · Product code: **DXT** · Cardiovascular
Source: https://www.510kdatabase.net/k092896/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Sep 21, 2009
Decision date	Oct 29, 2010
Days to decision	403 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nemoto Kyorindo Co., Ltd.**
Location	Tokyo, JP
Contact	JIM KNIPFER
510(k) history	8 submissions · 8 cleared · 2005-2024