FDA 510(k) Premarket Notification

K100919 PRO FOCUS 2202, PRO FOCUS 2202 UV MODEL: TYPE 2202

CLEARED

Dec 16, 2011
623 days to decision

K100919 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k100919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 2, 2010
Decision date	Dec 16, 2011
Days to decision	623 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**B-K Medical Aps**
Location	Herlev, DK
Contact	RANDI HAUERBERG
510(k) history	11 submissions · 11 cleared · 2007-2014