FDA 510(k) Premarket Notification

K142505 ClearPoint System

CLEARED

Oct 21, 2015
411 days to decision

K142505 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k142505/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 5, 2014
Decision date	Oct 21, 2015
Days to decision	411 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mri Interventions, Inc.**
Location	Irvine, CA, US
Contact	E F Waddell
510(k) history	14 submissions · 14 cleared · 2011-2020