FDA 510(k) Premarket Notification

K140868 STRYKER KWIC NEEDLE

CLEARED

Jun 5, 2014
63 days to decision

K140868 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k140868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Apr 3, 2014
Decision date	Jun 5, 2014
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthovita, Inc.**
Location	Malver, PA, US
Contact	John Urtz
510(k) history	23 submissions · 23 cleared · 2001-2017