FDA 510(k) Premarket Notification

K161704 Phasor Drill

CLEARED

Dec 1, 2016
164 days to decision

K161704 · Product code: **HBE** · Neurology
Source: https://www.510kdatabase.net/k161704/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Jun 20, 2016
Decision date	Dec 1, 2016
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biotex, Inc.**
Location	Houston, TX, US
Contact	RICHARD WAITE
510(k) history	10 submissions · 10 cleared · 2006-2024