FDA 510(k) Premarket Notification

K032303 STRYKER CONSOLIDATED OPERATING ROOM EQUIPMENT (CORE) SYSTEM

CLEARED

Jan 16, 2004
175 days to decision

K032303 · Product code: **HBE** · Neurology
Source: https://www.510kdatabase.net/k032303/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Jul 25, 2003
Decision date	Jan 16, 2004
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Instruments**
Location	Kalamazoo, MI, US
Contact	JEAN W SHEPPARD
510(k) history	73 submissions · 73 cleared · 1994-2026