

K191049 Stryker MIS and Footed AttachmentsJun 18, 2019
60 days to decisionK191049 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k191049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Apr 19, 2019
Decision date	Jun 18, 2019
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Corporation
Location	Malwah, NJ, US
Contact	Paminder Khurmi
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...