FDA 510(k) Premarket Notification

CLEARED

K112593 STYKER CONSOLIDATED OPERATING ROOM EQUIPMENT (CORE) SYSTEM

May 1, 2012
237 days to decision

K112593 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k112593/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Sep 7, 2011
Decision date	May 1, 2012
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	MICHELLE JUMP
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...