FDA 510(k) Premarket Notification

K141935 STRYKER S2 DRILL

CLEARED

Sep 26, 2014
71 days to decision

K141935 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k141935/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Jul 17, 2014
Decision date	Sep 26, 2014
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	VISHAL KANANI
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...