

K232938 Traus SSG30 Surgical SystemSep 16, 2024
362 days to decisionK232938 · Product code: **HBC** · Neurology
Source: <https://www.510kdatabase.net/k232938/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Motor, Drill, Electric (HBC)
Date received	Sep 20, 2023
Decision date	Sep 16, 2024
Days to decision	362 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Saeshin Precision Co., Ltd.
Location	Seoul, KR
Contact	Gung San Nam
510(k) history	18 submissions · 18 cleared · 2009-2026

REGULATORY CONSULTANT

Consulting firm	E & M
Contact	Sanghwa Myung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov
