

**K052851 VOYAGER LINUX WITH TACTILE GUIDANCE SYSTEM
(TGS)**Nov 18, 2005
38 days to decisionK052851 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k052851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Oct 11, 2005
Decision date	Nov 18, 2005
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mako Surgical Corp.
Location	Weston, FL, US
Contact	WILLIAM F TAPIA
Website	https://www.stryker.com
510(k) history	33 submissions · 33 cleared · 2005-2026

Mako Surgical Corp. is a medical device manufacturer based in Weston, US. Now part of Stryker, the brand continues to operate under the parent company with a focus on robotic-assisted surgical systems. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. Orthopedic devices represent 88% of its submission portfolio. Mako's clearance history spans from 2005 to 2026, demonstrating sustained innovation in joint reconstruction and orthopedic surgery applications. Recent cleared devices include total knee and hip applica...

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Device record: <https://www.510kdatabase.net/k052851/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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