FDA 510(k) Premarket Notification

K231901 Hakon, Hakon Smart

CLEARED

Sep 28, 2023
92 days to decision

K231901 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231901/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 28, 2023
Decision date	Sep 28, 2023
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medical San Ind?stria DE Equipamentos M?dicos Ltda.**
Location	Lajeado, BR
Contact	Francis Laion de Padua
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**United Regulatory, LLC**
Contact	Rodrigo Abreu

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