FDA 510(k) Premarket Notification

K211821 DEKA Motus AZ

CLEARED

Jul 6, 2021
25 days to decision

K211821 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 11, 2021
Decision date	Jul 6, 2021
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**El.En Electronic Engineering Spa**
Location	Calenzano, IT
Contact	Paolo Peruzzi
510(k) history	27 submissions · 27 cleared · 2007-2023