FDA 510(k) Premarket Notification

K101904 SMARTXIDE 50 HS/MS

CLEARED

Jan 12, 2011
188 days to decision

K101904 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k101904/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 8, 2010
Decision date	Jan 12, 2011
Days to decision	188 days
Third-party review	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