FDA 510(k) Premarket Notification

K180193 DEKA SMARTXIDE Family (Smartxide Touch, Smartxide Punto)

CLEARED

Feb 21, 2018
28 days to decision

K180193 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180193/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 24, 2018
Decision date	Feb 21, 2018
Days to decision	28 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