FDA 510(k) Premarket Notification

K160312 FRAXIS DUO

CLEARED

Oct 28, 2016
266 days to decision

K160312 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k160312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 5, 2016
Decision date	Oct 28, 2016
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ilooda Co,., Ltd.**
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	YUN JUNG HA
510(k) history	16 submissions · 16 cleared · 2015-2024