FDA 510(k) Premarket Notification

K170738 InMode Diolaze XL

CLEARED

Aug 7, 2017
150 days to decision

K170738 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k170738/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 10, 2017
Decision date	Aug 7, 2017
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Inmode MD , Ltd.**
Location	Kfar Saba, IL
Contact	Amit Goren
510(k) history	21 submissions · 21 cleared · 2013-2021