FDA 510(k) Premarket Notification

K222352 Epildream HP 4000 MED

CLEARED

Apr 27, 2023
266 days to decision

K222352 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 4, 2022
Decision date	Apr 27, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**D.E.A Project S.R.1.**
Location	Mapello, IT
Contact	Nico Guerini
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Endo Engineering**
Contact	Chiara Violini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov