FDA 510(k) Premarket Notification

CLEARED

K201663 AcuPulse W CO2 Laser Systems, Delivery Devices and Accessories

Jul 16, 2020
27 days to decision

K201663 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201663/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 19, 2020
Decision date	Jul 16, 2020
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lumenis, Ltd.**
Location	Santa Clara, CA, US
Contact	Shlomit Segman
Website	http://www.lumenis.com/
510(k) history	28 submissions · 27 cleared · 2003-2021

Lumenis, Ltd. is a global leader in energy-based medical device solutions for aesthetic and vision care. The company develops and commercializes innovative laser, intense pulsed light (IPL), and radiofrequency technologies with a manufacturing facility in Santa Clara, California. Lumenis has received FDA 510(k) clearances from total submissions since 2003. The company specializes in General & Plastic Surgery devices, which represent 93% of its regulatory submissions. Its cleared portfolio includes ablative and fractional CO? laser systems, IPL platforms, and surgical lase...