FDA 510(k) Premarket Notification

CLEARED

K180597 AcuPulse (previously called AcuPulse 30/40 ST)

Apr 3, 2018
28 days to decision

K180597 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180597/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 6, 2018
Decision date	Apr 3, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary
Other names	AcuPulse 40W G; AcuPulse DUO

APPLICANT

Company	**Lumenis, Ltd.**
Location	Santa Clara, CA, US
Contact	Amaya De Levie
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...