FDA 510(k) Premarket Notification

K133891 MULTIPULSE TM+1470

CLEARED

Jan 30, 2015
406 days to decision

K133891 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k133891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 20, 2013
Decision date	Jan 30, 2015
Days to decision	406 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Asclepion Laser Technologies GmbH**
Location	Chelmsford, MA, US
Contact	ANTJE KATZER
Website	https://www.asclepion.com
510(k) history	29 submissions · 29 cleared · 2004-2026

Asclepion Laser Technologies GmbH is a leader in medical laser technology for aesthetic medicine and surgery. The company has operated since 1977 and serves customers in more than 70 countries. Asclepion maintains a manufacturing facility in Chelmsford, US, and specializes in innovative laser systems for dermatological and surgical applications. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. 93% of submissions focus on General & Plastic Surgery devices, reflecting the company's core expertise in this category. ...