FDA 510(k) Premarket Notification

K230990 Candela Vbeam Family of Pulsed Dye Lasers (Vbeam Prima, Vbeam Perfecta)

CLEARED

Jun 1, 2023
56 days to decision

K230990 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230990/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 6, 2023
Decision date	Jun 1, 2023
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Candela Corporation**
Location	Wayland, MA, US
Contact	Danielle Gibboney
510(k) history	8 submissions · 8 cleared · 2015-2024