FDA 510(k) Premarket Notification

K232192 Venus Versa PRO System

CLEARED

Sep 11, 2023
49 days to decision

K232192 · Product code: **ONF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232192/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jul 24, 2023
Decision date	Sep 11, 2023
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Venus Concept, Inc.**
Location	San Jose, CA, US
Contact	William H. McGrail
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Venus Concept USA, Inc.**
Contact	William H. McGrail

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