FDA 510(k) Premarket Notification

K191065 Venus VivaTM

CLEARED

Apr 1, 2020
345 days to decision

K191065 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 22, 2019
Decision date	Apr 1, 2020
Days to decision	345 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Venus Concept USA, Inc.**
Location	Sunrise, FL, US
Contact	Yoni Iger
510(k) history	11 submissions · 11 cleared · 2014-2022