FDA 510(k) Premarket Notification

K191073 Vein360 Endovenous Radiofrequency Ablation (RFA) Catheter

CLEARED

Oct 22, 2019
183 days to decision

K191073 · Product code: **NUJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (NUJ)
Date received	Apr 22, 2019
Decision date	Oct 22, 2019
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vein 360, LLC**
Location	Blue Ash, OH, US
Contact	Suzanne Meyer
510(k) history	4 submissions · 4 cleared · 2019-2023