FDA 510(k) Premarket Notification

K211203 Green OR Reprocessed Aquamantys Bipolar Sealer

CLEARED

Apr 7, 2022
350 days to decision

K211203 · Product code: **NUJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (NUJ)
Date received	Apr 22, 2021
Decision date	Apr 7, 2022
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Green Or, LLC**
Location	Golden Valley, MN, US
Contact	John Zehren
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Pathway, LLC**
Contact	Aaron Rogers

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