FDA 510(k) Premarket Notification

K223440 Plasma Pen (Plasma MD)

CLEARED

Mar 2, 2023
108 days to decision

K223440 · Product code: **QVJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223440/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Power Electrosurgical Devices For Skin Lesion Destruction (QVJ)
Date received	Nov 14, 2022
Decision date	Mar 2, 2023
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Plasma Pen (Plasma +)

APPLICANT

Company	**Plasma Concepts**
Location	Woburn, MA, US
Contact	Brendan Aarons
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Medicept, LLC**
Contact	Richelle Helman

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