FDA 510(k) Premarket Notification

K192813 Plasma IQ

CLEARED

Mar 6, 2020
157 days to decision

K192813 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192813/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 1, 2019
Decision date	Mar 6, 2020
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neauvia North America, Inc.**
Location	Raliegh, NC, US
Contact	Misty Williams
510(k) history	3 submissions · 3 cleared · 2020-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192813/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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