FDA 510(k) Premarket Notification

CLEARED

K221074 OptaBlate RF Generator, OptaBlate Probes, OptaBlate Microinfuser Infusion Device

Sep 16, 2022
157 days to decision

K221074 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 12, 2022
Decision date	Sep 16, 2022
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	Bruce Backlund
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...