FDA 510(k) Premarket Notification

K242266 PhotonBlade 3

CLEARED

Oct 21, 2024
81 days to decision

K242266 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242266/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 1, 2024
Decision date	Oct 21, 2024
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PhotonBlade 3 Smoke Evacuation

APPLICANT

Company	**Stryker Instruments**
Location	Kalamazoo, MI, US
Contact	Miriam Giltinan
510(k) history	72 submissions · 72 cleared · 1994-2026