FDA 510(k) Premarket Notification

K173503 Pollogen Legend System

CLEARED

Jun 11, 2018
210 days to decision

K173503 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k173503/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 13, 2017
Decision date	Jun 11, 2018
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pollogen, Ltd.**
Location	Binyamina, IL
Contact	Einat Shammai
510(k) history	18 submissions · 18 cleared · 2011-2025