FDA 510(k) Premarket Notification

K221522 HF-cables (resusable)

CLEARED

Jan 19, 2023
238 days to decision

K221522 · Product code: **GEI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 26, 2022
Decision date	Jan 19, 2023
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Winter & Ibe GmbH**
Location	Melville, NY, US
Contact	Lilly Omland
510(k) history	42 submissions · 42 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	**Olympus Surgical Technologies of the Americas**
Contact	Christina Flores

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