FDA 510(k) Premarket Notification

K210651 Resection Electrodes with HF cable

CLEARED

Aug 3, 2021
152 days to decision

K210651 · Product code: **FAS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k210651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrosurgical, Active, Urological (FAS)
Date received	Mar 4, 2021
Decision date	Aug 3, 2021
Days to decision	152 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	Katharina Campbell
510(k) history	42 submissions · 42 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	**Olympus Surgical Technologies America**
Contact	Christina Flores

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