FDA 510(k) Premarket Notification

K221293 E-Brik Visualization Assistant

CLEARED

Jul 7, 2022
64 days to decision

K221293 · Product code: **OCT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221293/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti Fog Solution And Accessories, Endoscopy (OCT)
Date received	May 4, 2022
Decision date	Jul 7, 2022
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jdi Surgical, Inc.**
Location	Highlands Ranch, CO, US
Contact	Dwight Lenox
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**University of Utah**
Contact	Srividya Pothana

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