FDA 510(k) Premarket Notification

K212322 Cellvizio I.V.E. system with Confocal Miniprobes

CLEARED

Aug 18, 2021
23 days to decision

K212322 · Product code: **OWN** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212322/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Jul 26, 2021
Decision date	Aug 18, 2021
Days to decision	23 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mauna Kea Technologies**
Location	Paris, FR
Contact	Aline Criton
Website	http://www.maunakeatech.com
510(k) history	18 submissions · 18 cleared · 2005-2022

Mauna Kea Technologies is a medical device company specializing in real-time cellular imaging systems. The company develops the Cellvizio® platform, which uses confocal laser endomicroscopy technology to enable in vivo visualization during endoscopic and surgical procedures. The company maintains a manufacturing facility in Paris, France. Mauna Kea Technologies has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus has centered on General & Plastic Surgery devices, which account for 94% of its submis...

REGULATORY CONSULTANT

Consulting firm	**Daniel & Daniel Consulting**
Contact	Michael A. Daniel

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