

K193416 Cellvizio I.V.E. with Confocal MiniprobesFeb 28, 2020
81 days to decisionK193416 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Dec 9, 2019
Decision date	Feb 28, 2020
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mauna Kea Technologies
Location	Paris, FR
Contact	Veronique Dentan
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...
