

K220477 Cellvizio 100 series system with confocal MiniprobesApr 11, 2022
52 days to decisionK220477 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	Feb 18, 2022
Decision date	Apr 11, 2022
Days to decision	52 days
Third-party review	No
Combination product	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](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k220477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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