

K171345 Cellvizio 100 Series Systems with Confocal Miniprobes

Aug 4, 2017
88 days to decisionK171345 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k171345/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	May 8, 2017
Decision date	Aug 4, 2017
Days to decision	88 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...

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Device record: <https://www.510kdatabase.net/k171345/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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