

**K141358 CELLVIZIO 100 SERIES WITH SYSTEM CONFOCAL MINIPROBES**Sep 25, 2014  
125 days to decisionK141358 · Product code: **OWN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k141358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Confocal Optical Imaging (OWN)
Date received	May 23, 2014
Decision date	Sep 25, 2014
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mauna Kea Technologies</b>
Location	Paris, FR
Contact	MICHAEL A DANIEL
Website	<a href="http://www.maunakeatech.com">http://www.maunakeatech.com</a>
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...