

K111047 CELLVIZIO 100 SERIES SYSTEM WITH CONFOCAL MINIPROBESAug 8, 2011
115 days to decisionK111047 · Product code: **OWN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k111047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Confocal Optical Imaging (OWN)
Date received	Apr 15, 2011
Decision date	Aug 8, 2011
Days to decision	115 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Mauna Kea Technologies, Inc.
Location	Newton, PA, US
Contact	CHRIS TIHANSKY
510(k) history	1 submissions · 1 cleared · 2011-2011

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