

**K191144 Cellvizio 100 Series System with Confocal Miniprobes**Jan 24, 2020  
269 days to decisionK191144 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191144/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Confocal Optical Imaging (OWN)     |
| Date received         | Apr 30, 2019                       |
| Decision date         | Jan 24, 2020                       |
| Days to decision      | 269 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Mauna Kea Technologies</b>   |
| Location       | Paris, FR   |
| Contact        | Veronique Dentan  |
| 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...

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