

**K153671 Family of CoolGlide Aesthetic Lasers**Mar 9, 2016  
79 days to decisionK153671 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153671/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Dec 21, 2015                            |
| Decision date         | Mar 9, 2016                             |
| Days to decision      | 79 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cutera, Inc.</b>   |
| Location       | Brisbane, CA, US  |
| Contact        | Julia Brown   |
| Website        | <a href="http://www.cutera.com/">http://www.cutera.com/</a> |
| 510(k) history | 31 submissions · 31 cleared · 2004-2025                     |

Cutera, Inc. is a medical device manufacturer specializing in aesthetic and surgical laser systems. The company operates with a manufacturing facility in Brisbane, US, and maintains a global presence across North America, Europe, and Australia. Cutera has established a strong regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The vast majority of its submissions focus on General & Plastic Surgery devices, reflecting the company's core expertise in this category. The most recent cle...

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