

**K153727 INTRAcel Premium Fractional RF Micro Needle (FRM) System**

Jul 21, 2016  
206 days to decision

K153727 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k153727/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 28, 2015
Decision date	Jul 21, 2016
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jeisys Medical, Inc.</b>
Location	Littleton, CO, US
Contact	HYOSEOK LEE
510(k) history	15 submissions · 15 cleared · 2008-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k153727/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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