

# **K193232 Emprint Ablation System with Thermosphere Technology, Emprint SX Ablation Platform with Thermosphere Technology**

Feb 13, 2020  
80 days to decisionK193232 · Product code: **NEY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k193232/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Nov 25, 2019
Decision date	Feb 13, 2020
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	Hilla Debby
510(k) history	89 submissions · 86 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193232/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026