

K203303 Emprint SX Ablation Platform with Thermosphere TechnologyDec 17, 2020
38 days to decisionK203303 · Product code: **NEY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k203303/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Ablation, Microwave And Accessories (NEY) |
| Date received | Nov 9, 2020 |
| Decision date | Dec 17, 2020 |
| Days to decision | 38 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien, LLC |
| Location | Mansfield, MA, US |
| Contact | Liron Bar-Yaakov |
| 510(k) history | 89 submissions · 86 cleared · 2010-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203303/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026