

**K083157 HS AMICA**Sep 29, 2009  
340 days to decisionK083157 · Product code: **NEY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083157/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Ablation, Microwave And Accessories (NEY) |
| Date received         | Oct 24, 2008                                      |
| Decision date         | Sep 29, 2009                                      |
| Days to decision      | 340 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>H.S Hospital Service S.P.A</b>     |
| Location       | Boca Raton, FL, US                    |
| Contact        | LUCIO IMPROTA                         |
| 510(k) history | 6 submissions · 6 cleared · 2004-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083157/> 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 May 26, 2026