

## K213067 Solero Microwave Tissue Ablation (MTA) System and Accessories

Dec 3, 2021  
71 days to decisionK213067 · Product code: **NEY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k213067/>

### SUBMISSION DETAILS

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Special   |
| Device classification | System, Ablation, Microwave And Accessories (NEY) |
| Date received         | Sep 23, 2021                                      |
| Decision date         | Dec 3, 2021                                       |
| Days to decision      | 71 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

### APPLICANT

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|                |   |
|----------------|---|
| Company        | <b>AngioDynamics, Inc.</b>  |
| Location       | Glens Falls, NY, US   |
| Contact        | Kasey E Newcomb   |
| Website        | <a href="http://www.angiodynamics.com/">http://www.angiodynamics.com/</a> |
| 510(k) history | 87 submissions · 82 cleared · 1995-2025                                   |

AngioDynamics, Inc. is a global leader in vascular and oncology medical technologies, with a manufacturing facility in Glens Falls, US. The company develops advanced devices addressing blood flow restoration, cancer therapies, vascular access, and varicose vein treatment. AngioDynamics has received FDA 510(k) clearances from total submissions since its first clearance in 1995. The company specializes in cardiovascular devices, with recent cleared products including mechanical aspiration systems, infusion systems, and angiographic catheters. The latest FDA 510(k) clearance...