

K182250 Solero MTA Cart, Solero MTA System, Solero microwave Tissue Ablation Applicator (14cm), , Solero microwave Tissue Ablation Applicator (19cm), Solero microwave Tissue Ablation Applicator (29cm)Feb 28, 2019
192 days to decisionK182250 · Product code: **NEY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Aug 20, 2018
Decision date	Feb 28, 2019
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AngioDynamics, Inc.
Location	Glens Falls, NY, US
Contact	Kasey Newcomb
Website	http://www.angiodynamics.com/
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...

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