

K183385 NanoKnife SystemJun 18, 2019
194 days to decisionK183385 · Product code: **OAB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Dec 6, 2018
Decision date	Jun 18, 2019
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Angiodynamics
Location	Marlborough, MA, US
Contact	Troy Roberts
Website	http://www.angiodynamics.com/
510(k) history	3 submissions · 3 cleared · 2014-2026

AngioDynamics is a global leader in vascular and oncology medical technologies, with a manufacturing facility in Marlborough, US. The company develops advanced devices addressing blood flow restoration, cancer treatment, and vascular interventions. AngioDynamics has received FDA 510(k) clearances from total submissions since its first clearance in 2014. The company's cleared devices span Gastroenterology & Urology, Cardiovascular, and General & Plastic Surgery categories. The latest clearance in 2026 confirms continued regulatory activity and product innovation. The compa...

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