

K253198 NanoKnife Generator (H78720300351US0)Mar 24, 2026
179 days to decisionK253198 · Product code: **OAB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Sep 26, 2025
Decision date	Mar 24, 2026
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Angiodynamics
Location	Marlborough, MA, US
Contact	Brandon Brackett
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...