FDA 510(k) Premarket Notification

K242687 NanoKnife Generator (H78720300301US0)

CLEARED

Dec 6, 2024
91 days to decision

K242687 · Product code: **OAB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242687/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Sep 6, 2024
Decision date	Dec 6, 2024
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NanoKnife Single Electrode Activation Probe, 15 cm (H787204001090); NanoKnife Single Electrode Activation Probe, 25 cm (H787204001100); NanoKnife Single Electrode Probe Spacer (H787204003010)

APPLICANT

Company	**AngioDynamics, Inc.**
Location	Glens Falls, NY, US
Contact	Brandon Brackett
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...

CLINICAL EVIDENCE - NCT04972097

Pivotal Study of the NanoKnife System for the Ablation of Prostate Tissue

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	121 patients (actual)
Study sites	17 sites
Condition studied	Prostate Cancer
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 14, 2024
Sponsor	Angiodynamics, Inc. (Industry)

Primary outcome

Rate of negative in-field biopsy at 12 months

Secondary outcome

Rate of negative in-field biopsy at 12 months as defined by the Delphi consensus criterion

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04972097