FDA 510(k) Premarket Notification

CLEARED

K101843 DURAMAX CHRONIC HEMODIALYSIS CATHETER AND PROCEDURE KIT

Oct 20, 2010
111 days to decision

K101843 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k101843/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Jul 1, 2010
Decision date	Oct 20, 2010
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**AngioDynamics, Inc.**
Location	Glens Falls, NY, US
Contact	DAVID A GREER
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...