

K202049 Python Catheter/Over-the-Wire Latis Graft Cleaning Catheter

Sep 7, 2021
410 days to decision

K202049 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k202049/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Embolectomy (DXE)
Date received	Jul 24, 2020
Decision date	Sep 7, 2021
Days to decision	410 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Applied Medical Resources Corporation
Location	Rancho Santa, CA, US
Contact	Andrew Powers Davis
Website	https://www.appliedmedical.com/
510(k) history	12 submissions · 12 cleared · 2017-2026

Applied Medical Resources Corporation is a medical device manufacturer specializing in minimally invasive surgical instruments and access systems, with a manufacturing facility in Rancho Santa, California. The company develops a broad portfolio of surgical tools for general, plastic, and gynecological procedures. Applied Medical has received FDA 510(k) clearances from total submissions since 2017. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared portfolio. The most recent clearance was in 2026, demons...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202049/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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