FDA 510(k) Premarket Notification

K223666 Ablacath™ Mapping Catheter

CLEARED

Mar 17, 2023
100 days to decision

K223666 · Product code: **MTD** · Cardiovascular
Source: https://www.510kdatabase.net/k223666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Dec 7, 2022
Decision date	Mar 17, 2023
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ablacon, Inc.**
Location	Denver, CO, US
Contact	Frank Rodriguez
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Honkanen Consulting, Inc.**
Contact	Laurie Lewandowski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov