

K201775 NuVision ICE CatheterMar 5, 2021
249 days to decisionK201775 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k201775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Jun 29, 2020
Decision date	Mar 5, 2021
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nuvera Medical, Inc.
Location	Los Gatos, CA, US
Contact	Robert Nardelli
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201775/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026