FDA 510(k) Premarket Notification

CLEARED

K251103 VeriSight Intracardiac Echocardiography Catheter (VSICE2D)

May 9, 2025
28 days to decision

K251103 · Product code: **OBJ** · Cardiovascular
Source: https://www.510kdatabase.net/k251103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Apr 11, 2025
Decision date	May 9, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VeriSight Pro Intracardiac Echocardiography Catheter (VSICE3D)

APPLICANT

Company	**Philips Image Guided Therapy Corporation**
Location	Colorado Springs, CO, US
Contact	Travis Pittman
510(k) history	4 submissions · 4 cleared · 2020-2026