

K200410 Reconnaissance PV .018 OTW Digital IVUS CatheterMay 22, 2020
93 days to decisionK200410 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k200410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Feb 19, 2020
Decision date	May 22, 2020
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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