

K262013 Kiba CTO Crossing Catheter

Aug 28, 2026
74 days to decision

K262013 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k262013/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jun 15, 2026
Decision date	Aug 28, 2026
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Reflow Medical, Inc.
Location	San Clemente, CA, US
Contact	Angela Lamprey
510(k) history	10 submissions · 9 cleared · 2016-2026