

K150865 Metacross RX PTA Balloon Dilitation CatheterAug 3, 2015
124 days to decisionK150865 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k150865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 1, 2015
Decision date	Aug 3, 2015
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KANEKA Corporation
Location	Tokyo, JP
Contact	Toshihiko Motomine
510(k) history	10 submissions · 10 cleared · 2015-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150865/> 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 31, 2026