

**K252702 Bioptimal Pulmonary Artery Monitoring Catheter
 (TD2502NF, TD2502NGF, TD2502NDF, TD2502NCF,
 TD2502NCGF, TD2502NDGF, TD2502NDCF, TD2502NDCGF,
 TD2502NXCF, TD2502NDXF, TD2502NXCGF, TD2502NDXGF,
 TD2502NDXCF, TD2502NDXCGF, TD2502-110NF,
 TD2502-110NGF, TD2502-110NDF, TD2502-110NCF,
 TD2502-110NDGF, TD2502-110NDCF, TD2502-110NCGF,
 TD2502-110NDCGF, TD2502-110NXF, TD2502-110NXGF,
 TD2502-110NDXF, TD2502-110NXCF, TD2502-110NDXGF,
 TD2502-110NDXCF ,TD2502-110NXCGF, TD2502-110NDXCGF,
 TD2602NF, TD2602N**

May 28, 2026
 274 days to decision

K252702 · Product code: **DQO** · Cardiovascular
 Source: <https://www.510kdatabase.net/k252702/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Aug 27, 2025
Decision date	May 28, 2026
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioptimal International Pte. , Ltd.
Location	Singapore, SG
Contact	Francis Joey Eduave
510(k) history	2 submissions · 2 cleared · 2025-2026
