FDA 510(k) Premarket Notification

CLEARED

Mar 28, 2024
266 days to decision

K232013 Aperta NSE PTA Balloon Dilatation Catheter (AW18-05040040/AA18-05040040, AW18-09040040/AA18-09040040, AW18-14540040, AW18-05050040/AA18-05050040, AW18-09050040/AA18-09050040, AW18-14550040, AW18-05060040/AA18-05060040, AW18-09060040/AA18-09060040, AW18-14560040 AW18-05070040/AA18-05070040, AW18-09070040/AA18-09070040, AW18-14570040, AW18-05080040/AA18-05080040, AW18-09080040/AA18-09080040, AW18-14580040)

K232013 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k232013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Jul 6, 2023
Decision date	Mar 28, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Goodman Co., Ltd.**
Location	Ridgefield, CT, US
Contact	Aida Kanechika
510(k) history	3 submissions · 3 cleared · 2001-2025

REGULATORY CONSULTANT

Consulting firm	**Infraredx, Inc.**
Contact	Nozomi Yagi

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov