FDA 510(k) Premarket Notification

K243944 Aperta NSE PTA Balloon Dilatation Catheter

CLEARED

Apr 22, 2025
123 days to decision

K243944 · Product code: **PNO** · Cardiovascular
Source: https://www.510kdatabase.net/k243944/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Dec 20, 2024
Decision date	Apr 22, 2025
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Infraredx**
Contact	Nozomi Yagi

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243944/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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