FDA 510(k) Premarket Notification

K220881 INOUE BALLOON A

CLEARED

Dec 18, 2022
268 days to decision

K220881 · Product code: **OZT** · Cardiovascular
Source: https://www.510kdatabase.net/k220881/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Mar 25, 2022
Decision date	Dec 18, 2022
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Toray Industries, Inc.**
Location	Chuo-Ku, JP
Contact	Satoshi Kakuyama
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Toray Industries (America), Inc.**
Contact	Yuya Shizume

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