FDA 510(k) Premarket Notification

K200560 InBody

CLEARED

Jan 6, 2021
308 days to decision

K200560 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k200560/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 4, 2020
Decision date	Jan 6, 2021
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inbody Co., Ltd.**
Location	Seoul, KR
Contact	Koeun Jung
510(k) history	4 submissions · 4 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

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