

K200560 InBodyJan 6, 2021
308 days to decisionK200560 · 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](https://accessdata.fda.gov)

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