

**K231174 BPBIO750**Aug 2, 2023  
99 days to decisionK231174 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231174/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 25, 2023
Decision date	Aug 2, 2023
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inbody Co., Ltd.</b>
Location	Seoul, KR
Contact	Kichul Cha
510(k) history	4 submissions · 4 cleared · 2020-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
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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