FDA 510(k) Premarket Notification

K230916 WeSensor

CLEARED

Oct 10, 2023
190 days to decision

K230916 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k230916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Apr 3, 2023
Decision date	Oct 10, 2023
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Picopack, Inc.**
Location	Daejeon, KR
Contact	Dong-Il Kim
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Lighten Bridge, LLC**
Contact	Edward Park

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

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Device record: https://www.510kdatabase.net/k230916/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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