FDA 510(k) Premarket Notification

K243143 E-PEN (E-PEN)

CLEARED

Apr 7, 2025
189 days to decision

K243143 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Sep 30, 2024
Decision date	Apr 7, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bomtech Electronics Co., Ltd.**
Location	Seoul, KR
Contact	Lee Junseok
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Corazon**
Contact	Seo Juntaek

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