FDA 510(k) Premarket Notification

K221233 DT-703

K221233 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k221233/

CLEARED

Jun 27, 2022
59 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Apr 29, 2022
Decision date	Jun 27, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ecotron Co., Ltd.**
Location	Seoul, KR
Contact	Sang Bong Lee
510(k) history	4 submissions · 4 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	**Mtechgroup**
Contact	Dave Kim

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221233/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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