FDA 510(k) Premarket Notification

K233457 RUS

CLEARED

Jul 12, 2024
266 days to decision

K233457 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k233457/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 20, 2023
Decision date	Jul 12, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hutom, Inc.**
Location	Seoul, KR
Contact	Heejoo Yun
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**LK Consulting Group USA, Inc.**
Contact	Priscilla Chung

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