FDA 510(k) Premarket Notification

K223639 VisAble.IO

CLEARED

Aug 28, 2023
266 days to decision

K223639 · Product code: **QTZ** · Radiology
Source: https://www.510kdatabase.net/k223639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Ablation Therapy Planning And Evaluation (QTZ)
Date received	Dec 5, 2022
Decision date	Aug 28, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Techsomed**
Location	Rehovot, IL
Contact	Dalia Dickman, PhD
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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