FDA 510(k) Premarket Notification

K203651 Cuptimize

CLEARED

Feb 26, 2021
74 days to decision

K203651 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k203651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 14, 2020
Decision date	Feb 26, 2021
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cuptimize, Inc.**
Location	Belleair Bluffs, FL, US
Contact	Noah Wollowick
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Michelle McDonough

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