FDA 510(k) Premarket Notification

K200315 Ziostation2

CLEARED

May 5, 2020
88 days to decision

K200315 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k200315/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 7, 2020
Decision date	May 5, 2020
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ziosoft, Inc.**
Location	Irvine, CA, US
Contact	Tsuyoshi Nagata
510(k) history	6 submissions · 6 cleared · 2007-2020

REGULATORY CONSULTANT

Consulting firm	**Ziosoft USA, Inc.**
Contact	Richard Ball

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