

K200315 Ziostation2May 5, 2020
88 days to decisionK200315 · 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](https://accessdata.fda.gov)

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