

K162002 Z-Box/Z-Tilt Breast and Thoracic Positioning Device, Z-Square Indexing System, Z-Foam, Z-Bar Index Bar, Z-Pulls Patient Hand Grip Overlay

Nov 1, 2016
104 days to decision

K162002 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k162002/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 20, 2016
Decision date	Nov 1, 2016
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zdi, Solutions, LLC
Location	Knoxville, TN, US
Contact	Zachary A. Dutton
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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