

K170540 DM-DensityFeb 23, 2018
365 days to decisionK170540 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k170540/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 23, 2017
Decision date	Feb 23, 2018
Days to decision	365 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Densitas, Inc.
Location	Halifax, CA
Contact	Mo Abdoell
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Emergogroup, Inc.
Contact	Ken Pilgrim

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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