

K211039 BIT-MotionDec 15, 2021
252 days to decisionK211039 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k211039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 7, 2021
Decision date	Dec 15, 2021
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dde Mri Solutions, Ltd.
Location	Tel Aviv, IL
Contact	Moti Sokolov
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT02812589**

Diffusion Tensor Breast MRI (DTI)

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	267 patients (actual)
Study sites	1 site
Condition studied	Breast Cancer
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 1, 2020
Sponsor	University Health Network, Toronto (Other)

Primary outcome

Validate DTI as a valuable adjunct to improve lesion characterization on breast MRI by using the difference in recall rates

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02812589