

K213735 dS Sentinelle Breast 16ch 1.5T CoilAug 8, 2022
252 days to decisionK213735 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k213735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Nov 29, 2021
Decision date	Aug 8, 2022
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Invivo Corporation (Business Trade Name: Philips)
Location	Florida, FL, US
Contact	Ann Lebar
510(k) history	6 submissions · 6 cleared · 2021-2023

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