

# Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252954

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Please provide the device trade name(s).

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MammoSightAI

Please provide your Indications for Use below.

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MammoSightAI is a software radiological workflow tool designed to assist radiologists in prioritizing exams within the standard-of-care image worklist for compatible FFDM and DBT screening mammograms. Utilizing an advanced artificial intelligence algorithm, MammoSightAI analyzes each mammogram and assigns a tag indicating the software's suspicion of at least one potentially suspicious finding. These assigned tags are seamlessly integrated into the hospital PACS or workstation, enabling worklist prioritization or triage to help radiologists focus on the most critical cases first.

MammoSightAI is intended for passive notification only and does not provide any diagnostic information beyond triage and prioritization. Thus, it is not intended to replace the review of images or be used on a stand-alone basis for clinical decision-making. The interpreting radiologist is responsible for reviewing each exam on a diagnostic viewer and evaluating each patient according to the current standard of care

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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