

Indications for Use

510(k) Number (if known): K072258

Device Name: BI-RADS Companion

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BI-RADS Companion™ (“BRC”) is a computer–aided image viewing and report generating tool designed to assist radiologists in the analysis of ultrasound images of breast masses by making the ACR “BI-RADS Classification Form and Lexicon®” (“ABCFL”) available in electronic format. The user can view any selected image from a case and segment the lesion from the background by applying a user selected threshold or outlining the lesion manually with a cursor.

The user can annotate, tag, measure, and record selected views. Under user control and review, the software electronically assembles reports from inputs selected by the user from the ultrasound ABCFL during the image interpretation process. The assembled report complies with the ABCFL for ultrasound. The output may be viewed and sent to electronic storage media, or standard film or paper printers or other document manipulation programs such as Adobe or Microsoft.

When used by a skilled radiologist, this device provides information that may be useful in image interpretation. Patient management decisions should not be based solely on forms generated by BRC.

The ultrasound images displayed by BRC must not be used for primary diagnostic interpretation.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)