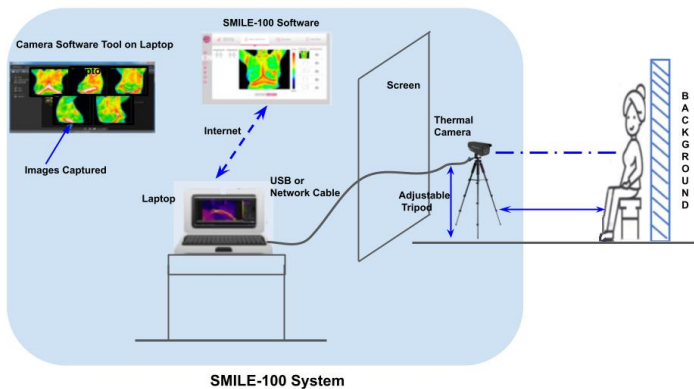


## Niramai bags US FDA clearance for medical device 'SMILE-100 System'

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**The first Indian company to get an US FDA clearance for a medical device used for women's health**



Niramai Health Analytix, a deep-tech Bengaluru-based healthcare startup offering a novel radiation-free, non-touch, accurate, breast cancer screening solution in India, has now received US FDA clearance for their first device called SMILE-100 System.

The SMILE-100 System is a breast thermography device that helps healthcare personnel to review, measure and analyze thermally significant indications in the breast region. It can be used in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel. It is intended for use as adjunctive diagnostic imaging for thermally significant indications in the breast region.

The SMILE-100 System assists experts to visualize high thermal activity patterns clearly demarcated on thermal images as hotspots and can enable healthcare professionals to make better decisions in breast cancer screening and diagnosis. Another unique feature of SMILE-100 is use of their patented artificial intelligence-based algorithms to check the quality of input thermal images, which can greatly reduce the errors in thermal image capture and enable low skilled health workers to confidently perform the imaging.