

**Exhibit 16 Summary of Safety & Effectiveness for  
*Shared Vision*<sup>™</sup> Image Display Software, Part Number SV 0015**

K961753

*Shared Vision* is a computerized, enhanced electronic Image Display Software System designed for clinical applications to allow physicians or other health care providers to remotely view and analyze patient Image Display data. This system is suited for various computer networks.

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As such, this device is a Class II device, having Classification Name, Monitor, Image Data, described as:

Product Nomenclature	Classification Number	Regulation Number
Cat Scanner	90JAK	892.1750
MRI	90LNH	892.1000
Radiographic	90KPR	892.1680
Fluoroscopy	90JAA	892.1659
Ultra Sound	90IYO	892.1560

*ImageLabs, Incorporated* has determined that this device is substantially equivalent to a *predicate* medical device which is currently in commerce and has been submitted to the FDA via K936179 as an electronic Image Display Software and is identified as the Winrad Teleradiology System manufactured by Line Imaging Systems from Atlanta, GA. A determination of substantial equivalency is based upon:

Both the *Shared Vision* and Winrad Teleradiology System are electronic Image Display Software for clinical applications, to allow physicians or other health care providers to remotely view and analyze patient image data.

Both devices use a computer program to display a pre-digitized patient image file. Both devices run under a computer operating system. Both devices use the computer operating system to access the displayed image.

Both devices output a display image that resembles a conventional image. Both devices retain an electronically stored sample. Both act on that sample using mathematical computations. Both use a proprietary algorithm. Both use computer programming in a computer operating system.

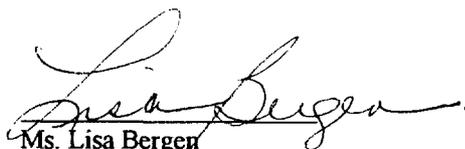
Neither device has claims, or is offered as having the reproduction equivalent of a radiographic image.

*Shared Vision* has benefited from design, development, testing, and production procedures that conform to Good Manufacturing Procedures. This device has performance characteristics substantially equivalent to its predicate device yet includes improvements to facilitate the various clinical applications for which it is intended.

This device is safe and effective for the applications for which it is intended and has been tested to confirm safety and efficacy. *ImageLabs Incorporated* continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

**CERTIFICATION**

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated device.



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