

K955891

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**Exhibit 14 Summary of Safety & Effectiveness for  
*CardioView*<sup>™</sup> Transtelephonic Software, Part Number 268-400-004**

*CardioView* is a computerized, enhanced electronic Transtelephonic Software System designed for clinical applications to allow physicians or other health care providers to remotely view and analyze patient ECG data. This system is suited for small to medium health care monitoring facilities. It offers a 12 lead ECG remote monitoring system which is more comprehensive than conventional single lead transtelephonic Software.

As such, this device is a Class II device, having Classification Name: Monitor, Electrograph, Product Code: 74FYW as described in 21 CFR Part 870.2340. **MICROMEDICAL INC.** 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 K925639 as an electronic Transtelephonic Software and is identified as *CardioMagic*<sup>™</sup> Software, marketed by Instrumedix.

A determination of substantial equivalence is based upon:

Both the *CardioView* and *CardioMagic*<sup>™</sup> are electronic Transtelephonic Software for clinical applications to allow physicians or other health care providers to remotely view and analyze patient ECG data.

Both devices use a remote user input device that retains the ECG signal and transmits it over the telephone lines. Both devices can use a switched telephone network. Both devices use a modem at the Host site to communicate with the remote device and uplink the data into the Computer. Both devices use a DOS based Computer which runs in *Windows*<sup>™</sup> to display data.

Both devices: output a display that resembles a conventional ECG display. Both devices retain a electronically stored sample. Both act on that sample using mathematical computations. Both use a proprietary algorithm. Both use computer programming in a *Windows*<sup>™</sup> environment.

Neither device have claims or, are offered as, laboratory analysis equipment. Both are for remote convenience and easy response.

The *CardioView* 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 application for which it is intended and has been tested to confirm safety and efficacy. **MICROMEDICAL INC.** 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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