DIGISONICS

K970402

MAR 26 1997

## 510(k) SUMMARY

### Doctors Review System

**Name of Submitter:**

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**Contact Person:**

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**Date of Summary:**

January 27, 1997

**Device and Common Names:**

Device Proprietary Name: Doctors Review System
Common Name: Review and Reporting System

**Device Description:**

Indications for Use

The Doctors Review System (DRS) is general purpose, standalone software for creating patient reports. It consists of Digisonics word processing software together with off-the-shelf computer equipment (PC, VCR, printer, etc.). Using the system, the physician reviews data (from other sources), notes clinical observations from sets of menus, and creates patient reports. Optional analysis programs are provided for quantitation of echo and cath lab data. No diagnoses are made by the software. It is not used for therapy or patient monitoring.



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User Characteristics

The review system is used by radiologists, cardiologists, obstetricians and gynecologists. The device is used in hospitals, outpatient clinics, and other clinical environments that need efficient review and reporting systems.

General Description

The Doctors Review System is sold either as software alone or as software together with PC based computer parts. The device is available in a variety of configurations, reflecting specific requirements of different specialities. An optional Search package is also available. This program searches the data base of stored reports and list those studies matching the search criteria specified. Links to a variety of ultrasound systems are available as options. The new digital image management option for capturing and displaying digital data is also available as an add-on to the various configurations.

**Substantial Equivalence**

The Doctors Review System is substantially equivalent to the following systems which are currently marketed:

- ATL Nova Microsonics - Image Vue DCR System
- TomTec - TomTec 90 with Echocardiography Offline Review
- General Electric - RT 4000 Data Management Center
- On-Time Medical - Click*View

All of these devices include review and reporting capabilities. The first two devices include cardiology analysis and digital image management options. The last two devices include obstetrics/gynecology calculations.

**Test Discussion:**

Testing was performed according to internal company procedures. Software verification and validation was done at the module, integration and system level according to written test protocols established before testing was conducted. Test results are reviewed by designated professionals before software is approved for release.

**Test Conclusions:**

Validation and verification results support the conclusion that the software performance satisfies all functional and system specifications.