510(K) SUMMARY
PREPARED JUNE 18, 2004

MANUFACTURER SUBMITTING 510(K) NOTIFICATION:

Mediware Dallas Service Center
Mediware Information Systems, Inc.
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DEVICE NAME:

Proprietary Name:	Instrument Interface Engine^{SM}, Release 1.0
Common Name:	Software, Blood Bank, Stand Alone
Classification Name:	Unclassified

PREDICATE DEVICES:

Mediware Information Systems, Inc.
HCLL, version 2.6
BK030078

DEVICE DESCRIPTION:

The IIE application is a stand-alone blood bank software device that aids in the management of patient ABO/Rh and antibody screen test results from a blood bank testing instrument (ABS2000) to a foreign stand-alone blood bank computer software system (HEMOCARE® and HCLL®).

INTENDED USE:

The Instrument Interface Engine (IIE) is a stand-alone computerized system intended to be used by trained personnel to aid in the transfer of patient test result data by a blood bank testing instrument to a blood bank system.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE:

The technological characteristics are similar in that the RDBMS, operating system and hardware are substantially equivalent to the predicate device.

Technological Comparison Chart:

Instrument Interface Engine	HCLL
Windows 2000	Windows 2000
Relational Database	Relational Database
Developed using Microsoft Visual Studio	Developed using Microsoft Visual Studio

SAFETY AND EFFECTIVENESS DATA:

The IIE application was developed using an established procedure for software development.

The assessment of the nonclinical (alpha) testing is that the IIE application design input requirements had been met. The design validation process demonstrated that the IIE application meets the requirements for the intended use.

Clinical/user site (beta) testing was conducted to validate the IIE system. Testing was conducted at a large clinical facility. The results of the beta testing demonstrated that the IIE system software met the required specifications and functioned as expected.

CONCLUSION:

The conclusions drawn for the nonclinical and clinical tests demonstrate IIE, Release 1.0, is substantially equivalent to the predicate device(s) when utilized within its intended use.