

510(k) SUMMARY

Prepared 8/3/95

MANUFACTURER SUBMITTING 510(k) SUMMARY:

Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018
(708) 825-2300
Contact: Manager, Regulatory Affairs

MANUFACTURING ADDRESS:

Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 60018

CLASSIFICATION NAME:

Software, Blood-Bank, Stand Alone Products, Product Code 75MMH

PRODUCT TRADE NAME:

Components and Distribution Information System

COMMON NAME:

CDIS

PREDICATE DEVICE:

The CDIS system is substantially equivalent to the Blood Inventory Management System which was on the market prior to May 28, 1976. This system was manufactured by Computer Sciences Corporation.

DEVICE DESCRIPTION:

The CDIS system is a stand-alone blood bank software device which aids in the manufacture of blood and blood components.

INTENDED USE:

The CDIS system is a computerized system intended to be used by trained personnel as an aid in the manufacturing and distribution of blood and blood components including derivative products. This product is intended for use with the IDM Donor Management Information System (DMIS).

TECHNOLOGICAL CHARACTERISTICS:

The CDIS system is technologically similar to the Blood Inventory Management System and both devices accomplish the same intended use.