

BK95-0045

510(k) SUMMARY
Prepared 8/8/95

MANUFACTURER SUBMITTING 510(K) SUMMARY:

Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 600 18
(708) 825-2300
Contact: Manager, Regulatory Affairs

MANUFACTURING ADDRESS:

Information Data Management, Inc.
9701 West Higgins Road
Rosemont, IL 600 18

CLASSIFICATION NAME:

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

PRODUCT TRADE NAME:

Donor Management Information System

COMMON NAME:

DMIS

PREDICATE DEVICE:

The DMIS systems is substantially equivalent to the Donor Deferral Register, a computerized national blood donor deferral registry system. This system was being marketed by the American National Red Cross in May, 1975 as evidenced by a JAMA article.

DEVICE DESCRIPTION:

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

INTENDED USE:

The DMIS system is a computerized system intended to be used by trained personnel as an aid in the tracking of donor demographic information and test results as well as donor deferral information. This system has been on the market since 199 1.

TECHNOLOGICAL CHARACTERISTICS:

The DMIS system is technologically similar to the Donor Deferral Register System and both devices accomplish the same intended use.