

Indications for Use

510(k) Number (if known)

K222320

Device Name

MedDream

Indications for Use (Describe)

MedDream is a software only Medical Image Management and Processing System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DI COM or HL 7 data, including mammographic images, and bio signals. MedDream also converts case related non-image documents, archives them as DICOM data and serves as a vendor neutral archive.

It supports the physician in diagnosis.

For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Note: Web-based image distribution and mobile device display of mammographic images are not intended for diagnostic purposes.

For users in the United States of America: Mobile device display is not intended for diagnostic purposes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."