K042353

NOV 2 4 2004

510(k) Summary

A. Manufacturer:

National Display Systems, Inc
16245 Vineyard Boulevard
Morgan Hill, CA 95037
USA

B. Submitted By:

Ron Hansen
Product Manager
National Display System, Inc.

C. Date of Preparation:

August 18, 2004

D. Contact Information:

Tel: 408.776.0085 Ext. 128
Fax: 408.776.9878

E. Classification Name:

System, image processing

F. Common Name:

Monitor, display, and others

G. Proprietary Name:

AXIS I Monochrome Display (1MP)
AXIS II Monochrome Display (2MP)
AXIS III Monochrome Display (3MP) and
AXIS V Monochrome Display (5MP)

H. Classification Number:

21 CFR 892.2050/Procode 90LLZ

I. Substantial Equivalence:

AXIS I (1MP) = Nova 1MP (NDS) K040310 and Coronis 1MP (Barco) K023340
AXIS II (2MP) = Nova 2MP (NDS) K040310; Coronis 2MP (Barco) K023322 and Dome C2 (Planar Systems) K032202
AXIS III (3MP) = Nova 3MP (NDS) K040310; Coronis 3MP (Barco) K013922 and Dome C3 (Planar Systems) K032638
AXIS V (5MP) = Nova 5MP (NDS) K040310; Coronis 5MP (Barco) K023341 and Dome C5i (Planar Systems) K032202

J. Device Description:

The AXIS Monochrome Display is a diagnostic display.

K. Intended Use:

The AXIS Monochrome Medical Displays are intended to be used to display and view digital images for review and analysis by trained medical practitioners. The AXIS V (5MP) display is currently not cleared in the U.S. for use with Full Field Digital Mammography (FFDM). The AXIS

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|---|---|
| | I (1MP), AXIS II (2MP) and AXIS III (3MP) displays are not intended for use with FFDM. |
| L. Technological Characteristics: | The AXIS Monochrome Display is a high resolution, Liquid Crystal Display (LCD) with electronic capabilities used for the review and analysis of high-resolution medical images. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Mr. Ron Hansen
Product Manager
National Display Systems, Inc.
16245 Vineyard Blvd.
MORGAN HILL CA 95037

Re: K042353
Trade/Device Name: AXIS I (1MP), II (2MP), III (3MP), and V (5MP) Monochrome Displays
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 20, 2004
Received: October 25, 2004

Dear Mr. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

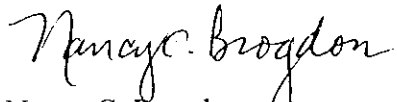
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): N/A

Device Name: AXIS FAMILY OF MEDICAL RADIOLOGY MONOCHROME DISPLAYS

Indications for Use:

The AXIS Radiology Monochrome Medical Displays are intended to be used to display and view digital images for review and analysis by trained medical practitioners. The AXIS 5MP display is currently not cleared in the U.S. for use with Full Field Digital Mammography (FFDM). The AXIS 1MP, 2MP and 3MP displays are not intended for use with FFDM.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042353