MAY 0 9 2002

CODONICS
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K021054

510(k) Summary **807.92(c)**

1 Submitter Information: **807.92(a)(1)**

1.1 Submitter:

Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.2 Manufacturing Facility:

Same as above

1.3 Representative:

Not applicable at this time

1.4 Contact:

Gary W. Enos, Phone:(440) 243-1198 / Fax : (440) 243-1334
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.5 Date: March 15, 2002

2 Device Name **807.92(a)(2) & 807.92(a)(3)**

2.1 Camera, Multiformat, Radiological

2.2 Classification Name: **Medical Image Hardcopy Devices**

Classification Number: 892.2040

2.3 Classification Code: LMC

2.4 Trade/Proprietary Name: Horizon® Series MEDICAL IMAGE HARDCOPY MULTIMEDIA PRINTERS: Horizon® Ci and Gs Medical Multimedia Dry Imagers

2.5 Predicate Devices: Codonics NP-1660 Series Medical Printers (Premarket notification K003481) and AGFA DryStar Models 3000 & 4500M (Premarket notification K012941)

3 Device Description **807.92(a)(4)**

3.1 Function

The Horizon® Series Imagers are dry, thermal, grey scale (Gs model) and grey scale/color (Ci model) direct thermal printer/imagers. The devices produce continuous tone, diagnostic quality B/W images on transmissive film and reflective incident light viewed media. The color images produced via dye-diffusion technology are photographic medical color matched quality.

3.2**Scientific Concepts:**

Digital images input directly or via Local Area Network is managed via communication standards including however not limited to FTP, TCP/IP, and DICOM. Images of a variety of digital formats are managed via industry standard format conversion software and image rendering algorithms including however not limited to TIFF, GIF, PCX, BMP, PBM, PGM, PPM, XWD, JPEG, SunRaster, SGI, Targa, DICOM, DEFF, and Postscript. Interpolation and scaling of images without Lossy data compression is employed in this device to maintain data integrity. Validated digital linear and visual linear routines and verified industry/modality specific Look Up Tables (LUTs) are applied to optimize color and CRT image hardcopy display results.

Imaging is accomplished via directly-modulated discrete-element thin-layer linear thermal print head technology. The recording medium is either heat sensitive silver in the case of DV grey scale film and DV DirectView reflective record imaging, or thermal heat activated dye-diffusion of color in the case of CV DirectView and Transparency/film record imaging. The action of heat on the grey scale media produces a black dye in the medium. The action of heat on the dye-diffusion media produces a precision mixing of colors, which diffuse the medium top layer. The image formation is accomplished without wet chemistry processing common to many laser film imaging systems in use today.

3.3**Physical And Performance Characteristics:**

In the case of medical image hard copy devices, important performance characteristics, which affect the effectiveness and safety, relate to the fidelity of the modulation transfer function. Spatial frequency response, grey scale resolution, density response and full image field uniformity combine to affect the final image. Characteristic response of thermal print head and film response must be mapped and compensated for to achieve suitable performance.

Pixel size (79μ for the Horizon® Series Imagers) produces a pixel resolution of 12.6 pixels/mm or 320 dpi. The grey scale resolution produces a palate of 4096 levels of discernable grey, while the color palate produces 256 levels of 16.7 millions colors. The SMPTE resolution and contrast pattern and uniform density response function confirms quality suitable for the intended medical imaging use.

4 Device Intended Use: **807.92(a)(5)**

4.1 The intended uses of the Horizon® Series Imagers is high resolution hard copy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes however is not limited to, digital radiography, nuclear medicine, ultrasound, CT, MRI, CR and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.

5 Device Technological Characteristics: 807.92(a)(6)

5.1 The characteristics of the Horizon® Series Imagers compare substantially to the Codonics NP-1660 Series Medical Printers (Premarket notification K003481), FUJI FM-DP 2636 Dry Imager (Premarket notification K962967), AGFA DryStar Models 3000 & 4500M (Premarket notification K012941), and Seiko ColorPoint 1720 (Premarket notification K991282) in system function and intended uses. The technology and applications are substantially equivalent to models of printers already cleared to market by the FDA, with the added convenience of combining multi-sized color and grey scale film and reflective media. Differences of note do not affect safety and effectiveness of the device, intended use, or application methods. The device operates in a manner substantially equivalent to other cleared devices in this category.

6 Testing and Equivalence: 807.92(b)(1), 807.92(b)(2) & 807.92(b)(3)

6.1 In the code implementation, electrical compliance tests, simulation, printer resolution pattern testing, and clinical studies, results and outcomes have been thoroughly reviewed with proper operation and intended functions verified. The device passed a series of electrical safety tests including UL 2601-1, CAN/CSA-C22.2 No 601.1-M90, IEC EN-60601-1, TUV/EN-60950:1992 and EN 60950/A1:1993. The devices comply with electromagnetic standards defined in EN-60601-1-2. Clinical tests have documented effective application and expected results consistent with predicate devices currently in commercial distribution.

Codonics believes the Horizon® Series Imagers to be substantially equivalent to Medical Image Hardcopy Devices currently in commercial distribution in the U.S. We have selected the Codonics NP-1660 Series Medical Printers (Premarket notification K003481) and AGFA DryStar Models 3000 & 4500M (Premarket notification K012941) as the predicate devices for our claim of substantial equivalence, Attachment 6 contains information describing these predicate devices and provides a comparison of the Horizon® Series Imagers to the predicate device(s) and describes how any differences of note are substantially equivalent.

7 Hazard Analysis and Safety Concerns

7.1 Hazard analysis on this product has been performed throughout the definition, design, and testing phases of the product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes and their effects
- Development of methodologies to control the occurrence of hazards and to constrain their effects;
- Determine any effect on patient safety and system effectiveness

The potential hazards associated with this software product are not different than those of other multiformat hardcopy image components. These are primarily related to the failure of computer system components, and may be variously obviated by decisions taken by the end users of the product. None of the failures are expected to materially contribute to patient death or injury.

It is our conclusion that no hardware or software component, operating in a properly configured environment, whose latent design defect would be expected to result in death or injury of the patient. Thus the "level of Concern" is "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

Mr. Gary W. Enos
Director, New Business Development
Codonics, Inc.
17991 Englewood Drive
MIDDLEBURG HEIGHTS OH 44130

Re: K021054
Trade/Device Name: Codonics Horizon® Ci Medical Multimedia Dry Imager
Condonics Horizon® Gs Medical Multimedia Grey Scale Dry Imager
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical Image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: March 27, 2002
Received: April 1, 2002

Dear Mr. Enos

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

Enclosure

510(k) Number (if known): K021054

Device Name: Horizon® Series MEDICAL IMAGE HARDCOPY MULTIMEDIA PRINTERS

Models: Horizon® Ci Color and Grey Scale Multimedia Imager
Horizon® Gs Grey Scale Multimedia Imager

Indications For Use:

The intended uses of the Horizon® Series Imagers is high resolution hard copy imaging of digital image source material and through the conversion of electronic signals from a wide variety of direct/indirect medical imaging modality outputs. The hardcopy output includes however is not limited to, digital radiography, nuclear medicine, ultrasound, CT, MRI, CR and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. The system is intended for use by medical radiologists, imaging modality specialists, and communications to referring physicians.

The intended uses are identical to the Codonics NP-1660 Series Medical Printers (Premarket notification K003481) as a combined color, film, reflective media imager. The intended uses are identical to the FUJI FM-DP 2636 Dry Imager (Premarket notification K962967) and AGFA DryStar Model 4500M ((Premarket notification K012941) in terms of dry radiological output devices with the addition of 14 x 17 media formats.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021054