K060440

MAR 16

Attachment 1
Summary of Safety and Effectiveness

*Attachments labeled "CONFIDENTIAL" as follows: Codonics, Inc. regards the information defined as part of this Attachment to be a trade secret and confidential in nature.

K060440

CODONICS
We bring the future into focus

510(k) Summary-Special **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:**

Alan DeSantis, Phone:(440) 243-1198 / Fax : (440) 243-1334
17991 Englewood Drive
Middleburg Heights, Ohio 44130

1.5 **Date:** February 17, 2006

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

Device Modification to **Cleared Device K021054**
Model Horizon XL- Long Film Imager
Model Horizon XL-X Various Models TBD

2.5 **Predicate Devices:** Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054

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

3.1 **Function**

The Horizon® Series Imagers are dry, thermal, grey scale 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.

The Horizon® XL provides the capability to image True Size Long films used in Orthopedic applications, particularly in spine and long bone studies. These have been traditionally performed utilizing contact-screen film radiography utilizing special long, light-sensitive x-ray films in special long film/screen cassettes. As more imaging departments and centers become committed to PACS implementation and the application of digital radiography (CR and DR) acquisition, Horizon® XL brings long films into the all-digital world.

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:**

The Horizon® XLSeries Imagers are high resolution hard copy imagers of digital image source material substantially equivalent to the Codonics Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054) 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 capability to image 14" x 36" and 14" x 51" true size film and (TBD) reflective media. The Horizon® Series Imagers output diagnostic quality hardcopy images from digital sources over LAN; indirect or direct digital capture devices including Computed Radiography (CR) and Digital Radiography (DR). A multitude of digital formats include TIFF, GIF, PCX, BMP, PBM, PGM, PPM, XWD, JPEG, SunRaster, SGI, Targa, DICOM, DEFF, and Postscript. Lossy data compression is not employed in this device.

The system software is used to control the image management and machine functions, including densitometry compensation of printing power with film & media characteristics.

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

4.1 The intended uses of the Horizon XL is identical to the Codonics Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054) as a combined color, film, reflective media imager. 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 addition of 14" x 36" and 14" x 51" true size "long" film " film permits digital direct orthopaedic application hardcopy including diagnosis and analysis of scoliosis, weight

bearing spine/hip/knee, and long bone/hip Prosthetic and orthopedic appliances work-up and surgical planning. Horizon XL is applicable to true-size hardcopy of whole body CT, MRI and Angiographic and Venous flow imaging procedures.

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

5.1 The characteristics of the Horizon XL model imagers compare substantially to the Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054) 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 with capability to image 14" x 36" and 14" x 51" true size "long" film for digital direct orthopaedic application hardcopy. Additional image memory, film transport software to permit longer film handling, modified film and film feed trays, mechanical extender arms to direct long film output to the external catch bin have been added to the standard Horizon Series imagers. Differences of note do not affect safety and effectiveness of the device, general radiographic imaging intended uses, or application methods. The device operates in a manner substantially equivalent to other cleared 892.2040 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 XL Model Imagers to be substantially equivalent to Medical Image Hardcopy Devices currently in commercial distribution in the U.S. We have selected Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054) as the predicate device for our claim of substantial equivalence, Attachment 6 contains information describing these predicate devices and provides a comparison of the Horizon XL Imagers to the predicate device 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 the Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054) 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

MAR 16 2006

Mr. Alan DeSantis
Director, Quality and Regulatory Affairs
Codonics, Inc.
17991 Englewood Drive
MIDDLEBURG HEIGHTS OH 44130

Re: K060440
Trade/Device Name: Horizon® XL Medical Long Film Imager, Image Hardcopy Multimedia Printers
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: February 17, 2006
Received: February 21, 2006

Dear Mr. DeSantis:

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/industry/support/index.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): K060440

Device Name: Horizon® XL MEDICAL Long Film Imager IMAGE HARDCOPY MULTIMEDIA PRINTERS

Models: Model Horizon XL- Long Film Imager

Indications For Use:

The intended uses of the Horizon XL are identical to the Codonics Horizon® Series Medical Hardcopy Dry Imagers (premarket notification K021054); high resolution hard copy imaging of digital image source material combining color, film, reflective media in one imager. 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 addition of 14" x 36" and 14" x 51" true size "long" film and (TBD) reflective Direct Vista Paper media permits digital direct orthopaedic application hardcopy including diagnosis and analysis of scoliosis, weight bearing spine/hip/knee, and long bone/hip Prosthetic and orthopedic appliances work-up and surgical planning. Horizon XL is applicable to true-size hardcopy of whole body CT, MRI and Angiographic and Venous flow imaging procedures.

(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)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060440