OCT 13 2004

[redacted]

SUMMARY

Submitter's Information:
CNC Imaging, Inc.
679-E South State College Blvd
Fullerton, CA 92831
714-447-9560
714-447-9572

Name of contact person: KORINA A. AKHONDZADEH
REGULATORY SPECIALISTS, INC.
1559 Eden Court
San Elijo Hills, CA 92078
760-798-9642
korina@regulatoryspecialists.com

Date the summary was prepared: September 27, 2004

Name of Device:

Trade/Proprietary Name: CDX Digital X-ray Imaging System
Common/Usual Name: Intraoral Digital X-ray sensor
Classification Name: Extraoral Source Dental X-ray, Digital System

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Description of the device:

Digital Dental intraoral Xray Sensor

This device is intended to be used for dental radiographic examination for the diagnosis of diseases of the teeth, jaw, and oral structures.

Indications:

Indications for Use (from labeling): The CDX Digital X-ray Imaging System is intended to be used with standard X-ray systems to collect dental x-rays photos and convert them into electronic data that may be stored, viewed, and manipulated by dentists for the diagnosis of diseases of the teeth, jaw, and oral structures

Summary of the technological characteristics of our device compared to the predicate device:

The predicate Dr. Suni Digital Radiography System K021718, manufactured by Suni Imaging Microsystems, Inc. and CNC Imaging, Inc. CDX Digital X-ray Imaging System were compared and found to have similar technological characteristics and to be equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 3 2004

CNC Imaging, Inc.
% Ms. Korina A. Akhondzadeh
Regulatory Specialist
Regulatory Specialist, Inc.
1559 Eden Court
SAN ELIJO HILLS CA 92078

Re: K042736
Trade/Device Name: CDX Digital X-ray Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: September 28, 2004
Received: October 1, 2004

Dear Ms. Akhondzadeh:

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

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

Enclosure

CNC Imaging

510(k) Number (if known): K042736

Device Name:

Indications For Use:

The CDX Digital X-ray Imaging System is intended to be used with standard digital X-ray systems to collect dental x-rays photos and convert them into electronic impulses that may be stored, viewed, and manipulated by dentists for the diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042736