510(k) Summary K040556

1. Company Identification

Eastman Kodak Company
Health Imaging Group
343 State Street
Rochester, NY 14650
Establishment Registration: 1317267

Practiceworks, Inc., an Eastman Kodak company
1765 The Exchange
Atlanta, GA 30339
Establishment Registration: 1226003

2. Contact Person

Donald Ellis
Director, Regulatory Affairs and Quality Systems

3. Device Name

TROPHYPAN/TROPHYPAN C System with the *Orthoimaging/OMS Imaging* System accessory

4. Device Classification

Class II
Product Code: EHD

5. Intended Use

The PracticeWorks *TROPHYPAN/TROPHYPAN C System* with the *Orthoimaging/OMS Imaging* System accessory is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce dental radiographic X-ray images of the dento-maxillo-facial area and store these images along with relevant patient examination information for use by dentists.

6. Device Description

The *TROPHYPAN/TROPHYPAN C System* is a panoramic extra-oral dental x-ray system, already marketed in the United States. *Orthoimaging and OMS Imaging software* consist of patient management software for dental, orthodontic, and oral surgery practices. By using the *TROPHYPAN/TROPHYPAN C* System with the *Orthoimaging/OMS Imaging System* accessory, the dentist can acquire radiographic images of the dentomaxillofacial region, visualize anatomical structures through the use of a computer display and store the information electronically in a clinical software program that enables dental offices to keep records of

hard and softcopy charts, treatment plans, clinical notes, and clinical exam data.

7. Substantial Equivalence

The modifications to the *TROPHYPAN/TROPHYPAN C* do not affect the materials, intended use, operating principles, or manufacture of the system as previously cleared. The indications for use and labeling have been modified but are substantially equivalent to the original device. The modification to the TrophyPand C consists of the addition of *Orthoimaging/OMS Imaging* software accessory for image archiving and management.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Mr. Donald Ellis
Director, Regulatory Affairs
& Quality Systems
Eastman Kodak Company
343 State Street
ROCHESTER NY 14650

Re: K040556
Trade/Device Name: TrophyPan C with Orthoimaging/OMSimaging Accessory
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: March 1, 2004
Received: March 17, 2004

Dear Mr. Ellis:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

Indications for Use

K040556

510(k) Number (if known):

The PRACTICEWORKS, *TROPHYPAN/TROPHYPAN C* System with the ***Orthoimaging System*** accessory is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce dental radiographic X-ray images of the dento-maxillo-facial area and store these images along with relevant patient examination information for use by dentists.

By using the *TROPHYPAN/TROPHYPAN C* System with the ***Orthoimaging System*** accessory, the dentist can acquire radiographic images of the dentomaxillofacial region, visualize anatomical structures through the use of a computer display and store the information electronically in a clinical software program that enables dental offices to keep records of hard and softcopy charts, treatment plans, clinical notes, and clinical exam data

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Concurrence of CDRH, Office of Device Evaluation

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040556