FEB - 2 2004

510(K) SUMMARY
OrthoPACS
December 10, 2003

1. SUBMITTER:

eTrauma.com Corporation
1425 East Newport Center Drive
Deerfield Beach, FL 33442
Telephone: 877-387-2862
Contact: Dan Hodgeman, President
Date Prepared: December 10, 2003

2. DEVICE:

Trade name:	OrthoPACS
Classification Name:	Picture Archiving and Communications System
Classification Number:	892.2050
Product Code	LLZ
Common Name:	Medical Image Management System
Classification:	Class II
Classification Panel:	Radiology

3. PREDICATE DEVICE:

The predicate devices used to determine substantial equivalence for the eTrauma OrthoPACS System were the Sectra Orthopedic Package (K031590) and the Cedara I-SoftView (K022881).

4. DEVICE DESCRIPTION:

eTrauma's OrthoPACS is a Digital Info-Imaging System for orthopaedic specific applications in office, private practice, surgery and clinics. The system allows orthopaedic surgeons to navigate quickly through a typical office day by using an efficient and fast system for viewing clinical images and retrieval of information regarding patient historicals whether local or residing on other digital information systems such as electronic medical record and/or practice management software. The four general classes of users for OrthoPACS include x-ray technicians, office managers, physicians and nurses.

OrthoPACS consists of the following components:

- Acquisition and Transmission Modules
- Viewing Station Module
- Storage Module
- RemoteImage Accessibility

5. INDICATIONS FOR USE:

OrthoPACS is intended for the manipulation and displaying of medical images by a suitable licensed and qualified healthcare professional. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards. OrthoPACS also uses such images, in conjunction with templates for prosthetic devices, for the purposes of choosing the nature and characteristics of the prosthetic device to be used when planning a potential surgical procedure.

6. COMPARISON OF CHARACTERISTICS:

All of the systems have the same intended use and are stand alone software packages that allow digital image processing and measurement capability. All systems transmit to remote viewing stations over a medical imaging network. None of the systems contact or require interaction with, the patient. All are used by health care professionals who interpret images and information being displayed or printed.

7. PERFORMANCE DATA:

The subject device is developed according to ISO 9001:1994 and complies with ISO 13485:1996.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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eTrauma.com Corporation
% Ms. Debbie Iampietro
President
QRC Consulting
7 Tiffany Trail
HOPKINTON MA 01748

Re: K033825
Trade/Device Name: OrthoPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 10, 2003
Received: December 10, 2003

Dear Ms. Iampietro:

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

510(k) Number (if known): K033825

Device Name: OrthoPACS

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033825