K042816

NOV 1 0 2004

510(k) Summary of Safety and Effectiveness

The Following 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

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Date:	August 18, 2004

807.92(a)(2) - Device Details:

Trade Name	TraumaCAD Release 1.00
Common Name	Picture Archiving and Communication (PACS) System
Classification	892.2050 Image Processing System
Class	II
Product Code	LLZ

807.92(a)(3) – Predicate Devices:

Medical Device Name	Applicant Name	510(k) Number	Classification
Orthoview	Meridian Technique Ltd	K032401	Class II, Product code LLZ
Sectra Orthopedic Package	Sectra Imtec AB	KO31590	Class II, Product code LLZ

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

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807.92(a)(4) – Device Description:

Device Functions:

TraumaCAD is a software application to be used by licensed physicians for preoperative planning of orthopedic surgical procedures. The application can be used in a workstation or in a PC as standalone software.

The system allows the physician to import medical images, and to overlay them with templates of medical prosthesis and to perform measurements to facilitate surgical planning. The surgical plan is available on the hospital network, and can be sent to the Operating Room prior to surgery.

The TarumaCAD does not have any image acquisition or image storage functionality, this is the responsibility of the systems alongside which TraumaCAD. In addition the system does not specify the requirements for the prosthetic template - this is the responsibility of the prosthetic manufacturer.

807.92(a)(5) – Device Intended Use:

The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.

Non-Clinical Testing

A study entitled "The Accuracy of Digital (filmless) Templating in Total Hip Replacement" was performed comparing pre-operative planning methods for total hip procedures. 20 cases planned using standard acetate overlays and radiographs were compared with 20 cases using TraumaCAD to perform digital preoperative planning.

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It was found that using standard templating, sixty percent of implanted stems were the same size as templated, 30 percent were within one size, and 10 percent were within 2 sizes. With digital templating 65 percent were the same size, 23 percent were within 1 size and 11 percent were within two sizes. For acetabular components using acetate overlays, 40 percent of implanted cups were the same size as templated, 30 percent were within 2 mm, and 30 percent within 4 mm. Digitally, 47 percent were the identical size, 47 percent were within 2 mm, and 6 percent within 4mm. All postoperative films show good fit of the components and there were no intraoperative or postoperative fractures.

Thus the non-clinical testing of the pre-operative planning using TraumaCAD produces results comparable to planning using acetate overlays with the additional advantages of digital planning including ease of use, improved case documentation, access to a wider arrange of tools, and greater accessibillty.

807.92(a)(6) – Substantial Equivalence Comparison Table:

Parameter	OrthoView	Sectra Orthopedic Package	TraumaCAD
Computer	PC Compatible	Part of workstation and PC compatible	PC Compatible
Operating System	Windows	Same	Same
Image input	Can receive digital images from various sources	Same	Same
Number of images that can be simultaneously viewed on the screen	Four	One	One
Runs on server	Yes	Yes	Yes
Trauma module	No	No	Yes
Osteotomy module	No	No	Yes
Digital Prosthetic templates	Template overlay capability	Same	Same
	Interactive template positioning	Same	Same
	Automatic Scaling	Same	Semi-automatic
	Template support from manufacturers	Same	Same
	Permits template rotation	Same	Same
Pre-operative planning	Allowed	Same	Same
Patient contact	None	Same	Same
Control of life-saving devices	None	Same	Same
Human intervention for interpretation and manipulation of images	Required	Same	Same
Ability to add additional modules when available	Yes	Yes	Yes

Technological Characteristics

TraumaCAD will run on Windows 2000 or Windows XP.

Performance Data

The subject device is developed according to IS0 9001 :2000.

Conclusion

Similar to the predicate devices the TraumaCAD does not control life-sustaining equipment or contact the patient and does not alter the source data and original image. In addition all three require intervention of trained medical for process and interpretation of the images.

Based on the information supplied in this 510(k), we conclude that this device is safe, effective, and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2004

Orthocrat, Ltd.
℅ Mr. Robert Mosenkis
President
Citech
Medical Device Testing
and Consulting
5200 Butler Pike
Plymouth Meeting PA 19462-1298

Re: K042816
Trade/Device Name: TraumaCAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 28, 2004
Received: October 29, 2004

Dear Mr. Mosenkis:

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

2. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **TraumaCAD**

Indication For Use:

The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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 K042816