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k032169

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510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Cyber Orthology, Inc.
6301 Hughes Dr.
Sterling Heights, MI 48312

Phone: 586-264-9544
Fax: 586-264-9566

Contact Person: Dr. Djoldas Kuldjanov

Date of Summary: June 30, 2003

Trade Name: CyberOrthology Carbon Fiber Composite Circular Fixation (CIRfix) Device (Half Ring)

Classification Name: APPLIANCE, FIXATION, NAIL/BLADE/PLATE COMBINATION, MULTIPLE COMPONENT

Classification Product Code: **KTT**

Predicate Device:

Ilizarov External Fixation System	K962808
External Fixation System	K870961

Intended Use:

Open and closed fracture fixation, nonunion, precise control of bone segments location including angulation, rotation, translation, lengthening, and shortening. The External Fixator also aids correction of bone deformities or defects associated with fractures and other pathological conditions of bone. The limb function is preserved if the External Fixator is properly applied.

Conclusion:

This device has equivalent intended use, has similar promotional claims, conforms to similar standards, and has equivalent technological characteristics to predicate devices.

Device Comparison Chart

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Comparison Items	CyberOrthology Carbon Fiber Composite Circular Fixation (CIRfix) device	Ilizarov External Fixation System K962808
Indication for Use	Part of external fixator aiding trophism in the correction of bone deformities/defects.	Same
Target population	Human of any gender and at the advanced walking age	Same
Design	Same physical design, except aesthetically and tactual more pleasing with improved impression of superior strength and safe mobility	Circular half-ring with overlapping ends to form a perfect ring when joined together by bolts and nuts
Material	Radiolucent Carbon Fiber Composite utilizing Randomly orientated, pre-impregnated carbon strands resulting in a carbon fiber content of better than 62%.	Radiolucent Carbon Fiber Composite featuring pre-determined fiber orientations and typically 55% carbon fiber content.
Performance	Comparatively tested, indicating 15%-20% superiority.	Compression Stiffness, (ASTM F-1746). 3-Point Bending. Cantilever Bending. Wire Pull-out Test.
Sterility	Shipped none-sterile & device may be sterilized as required by any method.	Same
Biocompatibility	The component is a none invasive external device and will not be used for implantation or contact with skin or soft tissues.	Same
Mechanical Safety	The test procedure &requirements allow for the appropriate amount of rigidity and stability.	Same
Chemical Safety	The device is indicated for use in clinical and common patient living environment not being exposed to harmful chemical elements	Same
Compatibility with other Devices	Compatible with all appropriate predicate devices	Compatible with specially designed frames, clamps, rods, couplings, pins, posts, bolts, washers, nuts, & others for the management of appropriate orthopedic surgeries.

Device Comparison Chart

Where used	The device is being used in hospitals and in patients surroundings and environments	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2003

CyberOrthology, Inc.
c/o Mr. Arthur Ward
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K032169
Trade/Device Name: CyberOrthology Carbon Fiber Composite Circular Fixation (CIRfix) Device (Half Ring)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: LXT
Dated: June 30, 2003
Received: July 21, 2003

Dear Mr. Ward:

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 (301) 594-4659. 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 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,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032169

Device Name: CyberOrthology Carbon Fiber Composite Circular Fixation (CIRfix) Device (Half Ring)

Indications For Use:

Open and closed fracture fixation, nonunion, precise control of bone segments location including angulation, rotation, translation, lengthening, and shortening. The External Fixator also aids correction of bone deformities or defects associated with fractures and other pathological conditions of bone. The limb function is preserved if the External Fixator is properly applied.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032169

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

(Optional Format 1-2-96)