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K020311
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Summary of Safety and Effectiveness

Rigid FX Orthopedics, Inc
3601 S. Congress
Bldg. B, #300
Austin, TX 78704
(512) 443-7770

Trade Name: ClearView™ Wrist Fixator

Common Name: Wrist Fixator

Classification Name: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030

Device Description: The device is a preassembled, mechanically adjustable external fixator and is available in three sizes (small, medium, and large). It is a four-piece construct consisting of a radiolucent polycarbonate plastic and applied to the bone with 2 pairs, with the option of a third pair, of self-drilling half-pins measuring 3mm x 110mm both cancellous and cortical. The half pins are used as bone anchors and are manufactured from medical grade stainless steel (316LVM).

Intended Use: The ClearView Wrist Fixator is indicated for single use for fixation of distal fractures in upper extremity applications. This device provides alignment, reduction, and stabilization of fractures, corrective osteotomies, and soft tissue deformities. Common fractures indicated for this use:

- fractures of the wrist with ligamentous instability
- comminuted intra-articular radius fractures
- post-traumatic reconstruction for joint stiffness
- Colles Fracture
- distal radius fractures (Types B and C)
- Frykman Type III, IV, VII and VIII radius fractures
- any wrist fracture requiring distraction

Comparable Features to Predicate Device(s): This device is similar in pin placement, materials, function, and indications to the Agee WristJack marketed by Hand Biomechanics Lab, Inc. (K992970), Synthes Articulating Distal Radius Fixator (K984498) and the DFS Wrist Fixator marketed by EBI/Orthofix (K993649).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2002

Mr. Mark Estrada
Vice President of Sales and Marketing
Rigid FX Orthopedics, Inc.
3601 S. Congress, Building B, Suite 300
Austin, TX 78704

Re: K020311
Trade/Device Name: ClearView™ Wrist Fixator
Regulation Number: 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: January 24, 2002
Received: January 29, 2002

Dear Mr. Estrada:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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). 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,

for Mark N. Melkerson

Celia 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): K020311

Device Name: ClearView™ Wrist Fixator

Indications For Use:

**ClearView™ Wrist Fixator**
**Indications For Use**

The ClearView™ Wrist Fixator is indicated for single use for fixation of distal fractures in upper extremity applications. This device provides alignment, reduction, and stabilization of fractures, corrective osteotomies, and soft tissue deformities. Common fractures indicated for this use:

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- any wrist fracture requiring distraction

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

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

510(k) Number K020311

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

(Optional Format 1-2-96)_