This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

REVIEWERS GUIDANCE CHECKLIST FOR ORTHOPEDIC EXTERNAL FIXATION DEVICES

Version #5

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I. GENERAL CONTENT OF A REVIEW

1. Follow the "Third Party Review: An Instruction Manual for Conducting Reviews of Premarket Notifications" supplied to Third Parties.

2. Follow the "Device Labeling Guidance" in the ODE Blue Book.

3. Use and modify as appropriate the boilerplate review memo in the ODE New Reviewer Training Manual.

II. DESCRIPTION OF PREDICATE(S) AND DEVICE UNDER REVIEW

1. Identify the type of bones to which the device is to attached (i.e., bone construct classification) and the types of frame and pin configurations (i.e., the frame limb access and frame pin configuration) as defined by ASTM F 1541 (see appendix 1 for examples of possible choices).
2. Compare the intended use of the device to the predicate(s). 21 CFR 888.3030 describes external fixation devices as single/multiple component metallic bone fixation appliances and accessories (product code KTT) that "...are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone." Limb lengthening and use in fixation of the hand have also been identified as preamendment intended uses. Any other intended uses should be removed or supported by clinical data.

   External fixation pins are classified in 21 CFR 888.3040 and have the following product codes: HTY (pin, fixation, smooth), JDW (pin, fixation, threaded) and JEC (component, traction, invasive).
3. Devices labeled for use in the spine or for dynamitization during bone healing, and devices which have a structural rigidity significantly lower than the predicate device or which claim MRI compatibility will not be reviewed by third parties. These complex issues require special analysis of the risks, and mechanical and/or animal testing may be necessary which is beyond the scope of this document.
4. List and classify each of the fixator elements (i.e., parts or components) as defined by STM F 1541. Possible choices and the suggested order that the components may be listed are given in appendix 2.
5. In addition to the above list, describe each device component as outlined in the checklist of material and design parameters in appendix 3.

III. COMPARE THE PREDICATE(S) AND DEVICE UNDER REVIEW

1. Compare the intended uses, design, materials, properties, etc. of the device under review to the same parameters of a predicate device, listing all similarities and differences between the two devices.
2. Give reasons why each difference does or does not add new or increased risks and complications, based on current engineering technology and clinical results published about external fixators as well as based on what has been previously cleared by FDA. Common complications involving external fixation devices include the following (Johnson, E.E., page 251):

   1. pin-tract infection,
   2. ring sequestrae,
   3. prolonged healing,
   4. distraction of the fracture site,
   5. delayed union,
   6. bone fracture.

3. Identify potential benefits of the new device compared to predicate devices.

4. Use the above information to justify test requirements as described below.

IV. DEVICE TESTING

The reviewer is responsible for assessing the information required to determine safety and effectiveness based on the particular design parameters of the device under review. The following are examples of tests that have been required for previous devices submitted to FDA. However, new information may suggest a different approach. The reviewer should justify test requirements and conclusions based on supportive references. If testing of the device is necessary as described below, a summary of the methods and results should be organized as suggested in appendix 4.

1. A device which has essentially the same design and materials as the predicate should not require testing unless there is new information which raises safety and effectiveness concerns.

2. The smooth or threaded fixation pin components (or their equivalent) that contact body tissues are always metal and are generally medical grade CoCrMo, Ti6Al4V or 316 LVM stainless steel. Other types of pin materials or combinations of materials should demonstrate a biological response at least as good as a predicate or substantially equivalent device when tested according to ISO 10993 for Medical Devices.

3. If the new device does not have the same or a higher estimated rigidity compared to the predicate device based on dimensions (given that the materials in the predicate have the same or higher elastic modulus compared to the new device) rigidity should be evaluated either in bench testing or in an animal model.

4. The static load to failure of the entire construct is only necessary for new designs in which the rigidity of the construct significantly differs from predicate designs.

5. If any interconnection design is not similar to a predicate design, loosening between parts at that interconnection should be evaluated. Cyclic loading is preferred, though static loading may be considered acceptable if properly rationalized. If the loads applied at the interconnection can be demonstrated to be the same as expected clinical loads, only the two joined parts need to be included in the test.

6. If the design under review has any stress risers not present in the predicate design, fatigue testing of the assembly should be performed, or a rationale for why such testing is not necessary should be presented.

7. Any reasonably known and available animal or clinical data about devices containing similar materials and designs should be summarized in a table. Additional animal or clinical data may be required if the bench testing methods or results of other tests raise concerns.

V. BIBLIOGRAPHY

Provide a bibliography if references are given (e.g., appendix 5).

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Appendix 1. Bone construct classification, frame limb access and frame pin configuration

The device under review and the predicate device should be described using the terminology defined in the ASTM F 1541 and organized as shown below (the section in ASTM F 1541 which defines the term is given). Any other features not included in this list should be added where appropriate.

Fixator-Bone Construct Classifications 6.3
- Long bone 6.3.1.1

Articular joint (arthrodesis) 6.3.1.2
Pelvis 6.3.1.3
Spinal 6.3.1.4
Halo (skull) 6.3.1.5
- Small bones
- Limb lengthening

Frame limb access 6.3.3
- Unilateral 6.3.3.1
- Multilateral 6.3.3.2
  - Bilateral
  - Triangular
  - Quadrilateral
  - Biplanar
  - Ring fixators 6.3.8
    - Half-ring
    - Circular or full-ring

Frame pin configuration
- One-plane 6.3.4.1
- Multi-plane 6.3.4.2

Appendix 2. Classification of fixator elements (or parts or components) in the system.

The fixator elements for both the device under review and the predicate device should be described using the terminology defined in the ASTM F 1541 and organized into a list as suggested below (the section in ASTM F 1541 which defines the term is given). Any other design features not included in this list should be added where appropriate.

- Anchorage elements 5.6
  - Wire-fixed 6.3.5.2
    - Wires 6.1.1
      - Stoppers ("olives")
  - Pin-fixed 6.3.5.1
    - Pins 6.1.2
      - Ends gripped by frame 6.1.2.1
        - Half-pins
        - Through-and-through pins or full-pins
      - Number of cortices penetrated
      - Surface 6.1.2.3
        - Smooth
        - Threaded
          - Self-drilling
          - Self-tapping
        - Type of bone to be penetrated 6.1.2.2
          - Cortical bone
          - Cancellous bone
      - Cross section 6.1.2.4
        - Constant
        - Shouldered
        - Tapered
      - Used individually or in clusters
    - Screws 6.1.3
    - Cortex clamps (or claws or prongs) 6.1.4
  - Hybrid coupling 6.3.5.3
- Bridge elements (bar or rod) 5.7, 6.2
  - Simple bridge elements 5.7.1
  - Complex bridge elements 5.7.2
    - Telescoping
    - Dynamic
- Connectors 5.8
  - Articulation 5.10
  - Non-adjustable joints 5.11
  - Independent control 6.3.7
  - Multi-pin clamps 6.3.7
  - Pin cluster 6.3.7

Appendix 3. Materials and design description of each component

For each part of each component of both the device under review and, as much as possible, the predicate device, provide the following:

names

model numbers

size ranges

identification on a photo or drawing of the fixator assembly (i.e., frame plus bony anchorage elements and their associated connectors (ASTM F 1541, 5.9) or fixator-bone construct and construct sub-unit (ASTM F 1541, 6.3.2))

drawing and/or description depicting the function and where it fits with other parts of the device and tissues

types of interfaces (i.e., articulating, fixed mating parts, coatings, tissues)

detailed engineering drawing with tolerances (as necessary)

material composition, to include the following:

sources of more detailed information (e.g., other FDA document submission numbers or other references)

description of the material (e.g., 316 LVM stainless steel), including processed condition (e.g. annealed, 20% cold worked)

name and number of applicable voluntary standards

differences between the final product and the standard

trade names (optional)

manufacturers (optional)

new processing methods, if any

Appendix 4. Organization of a summary of a mechanical bench testing report in a 510k review memo

The review memo should provide a summary of each mechanical bench testing report submitted in the 510k. This should include a list of the essential test parameters and results as well as the persons/labs generating the data. All reviews should be organized the same way. For example, a summary of each report should include (where applicable), but is not limited to the following:

REFERENCE
- Report title
- Investigators' names
- Facility Performing the test
  - Name
  - Address
  - Phone Number
- Dates
  - Test initiation
  - Test completion
  - Final report completion

TEST IDENTIFICATION
- Standard #
- Standard name
- Specific test name

SAMPLE DESCRIPTION (Design, Materials, Processing methods)
- Test sample description
- Control description
- Selection criteria
- Differences vis a vis final products

MEDIUM SURROUNDING THE SAMPLES BEFORE AND DURING TESTING
- Storage conditions prior to testing
- Volume
- Composition
- pH
- Temperature
- Flow
- Test model or subject which contacts the specimens

MECHANICAL LOADING
- Direction (e.g., normal to the longitudinal axis)
- Mode (e.g., 3 point bending)
- Load point (e.g., at the center of the rod)
- Magnitude (e.g., 10 lbs min., 100 lbs max.)
- Time (e.g., presoaked 10 days)
- Rate (e.g., 1 Hz)
- Cycles (e.g., 10^6)

TEST SETUP

- Schematic or photograph
- Description of grips or potting medium interfacing with samples
- Test equipment calibration (schedule, methods and data)
- Rationale for choices of parameters, values, etc.
- Methods of specimen examination (e.g., failure analysis)
- Number of samples tested, with statistical justification
- Chronological description of the test procedures
- Deviations from referenced protocols and standards

RESULTS

- Discussion of the data and possible mechanisms of failure
- List of conclusions
- Discussion of the objective/hypothesis
- Simplifications and assumptions and their clinical implications

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Appendix 5. Bibliography

ASTM F 1541 Standard Classification of External Skeletal Fixators

Anderson, R.C.: 'Final Report of the Structural Evaluation of the DDC Circular Fixator'. FDA Document K904932, Internat. Med. Prod. Corp. (pub.), 1990.

Aro, H.T.; et al.: 'Mechanical Characteristics of an Upper-Extremity External Fixator'. Clin. Orthop. Rel. Res., 253, pp. 240, Ap., 1990.

Egan, J.M.; Shearer, J.R.: 'Behavior of an External Fixation Frame Incorporating an Angular Separation of the Fixator Pins'. Clin. Orthop. Rel. Res., 223, pp. 265, Oct., 1987.

Evans, G.; et al.: 'External Fixation of fractures of the Tibia: Clinical Experience of a New Device'. Injury, 19, pp. 73, 1988.

Figgie, M.P.; et al.: 'Results of Reconstruction for Failed Total Elbow Arthroplasty'. Clin. Orthop. Rel. Res., 253, pp. 123, Ap., 1990.

Figgie, M.P.; et al.: 'The Results of Treatment of Supracondylar Fracture Above Total Knee Arthroplasty'. J. of Arthroplasty, 5, pp. 267, Sept., 1990.

Fjeld, T.O.; Steen, H.: 'Growth Retardation Following Experimental Limb Lengthening by Epiphyseal Distraction'. Acta Orthop. Scand., 61, pp. 52, Suppl.235, 1990.

ISO Test Methods for External Fixation Devices

Johnson, E.E.; et al.: 'Delayed Intramedullary Nailing After Failed External Fixation of the Tibia'. Clin. Orthop. Rel. Res., # 253, pp. 251, Ap., 1990.

Kelly, P.J.; et al.: 'Reaction of the Circulatory System to Injury and Regeneration'. Cli. Orthop. Rel. Res., 254, pp. 275, May, 1990.

Kenwright, J.: 'Leg Length Inequality'. Current Orthop., 3, pp. 176, July, 1989.

Nalebuff, E.A.: 'Surgery for Rheumatoid Arthritis: Upper Limb Surgery of the Wrist and Hand'. Current Orthop., 3, pp. 14, Jan., 1989.

Paley, D.: 'Problems, Obstacles, and Complications of Limb Lengthening by the Ilizarov Technique'. Clin. Orthop. Rel. Res., 250, pp. 81, Jan., 1990.

Schmalholz, A.: 'External Skeletal Fixation Versus Cement Fixation in the Treatment of Redislocated Colles' Fracture'. Clin. Orthop. Rel. Res., J.B. Lippincott Co. (pub.), 254, pp. 236, May, 1990.

Smith, S.R.; et al.: 'Effect of Fracture Fixation on Cortical Bone Blood Flow'. J. of Orthopaedic Research, 8, pp. 471, 1990.

Solgaard, S.: 'External Fixation or a Cast for Colles' fracture'. Acta Orthop. Scand., 60, pp. 387, Aug., 1989.

Whitelaw, G.P.; et al.: 'Ender rods Versus External Fixation in the Treatment of Open Tibial Fractures'. Clin. Orthop. Rel. Res., # 253, pp. 258, Ap., 1990.

Appendix 6. Sample review memo of an external fixation system

KEY WORDS ext wire ti 64 coa anodize color ss

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5 1 0 (k) R E V I E W

DATE February 21, 1997
FROM Xxx Xxxxxxxxx
TO File

DOCUMENT # K000000
SPONSOR Xxxxxxxx
DEVICE NAME Xxxxxxxx External Fixation System

CLASS KTT 2 888.3030 APPLIANCE, FIXATION, NAIL/BLADE/PLATE COMBINATION, MULTIPLE COMPONENT

DISEASE/USE Open and closed fracture fixation, nonunions, limb lengthening, soft and hard tissue deformities or defects. This material is for nickel sensitive patients.

REASON FOR APPLICATION: Change in materials (from 316 LVM SS to Ti-6Al-4V)

DECISION SE

The change in material did not significantly affect the rigidity or fatigue properties of the device. The static strength was lower for the Ti-6Al-4V wire, however:

Even the xxxx N failure load of the Ti alloy wire exceeds 3 times body weight (2000 N) by 900 N, i.e., xx% of 2000 N.

More than one wire is used in parallel, so the load is shared.

STERILITY nonsterile
FILE bonfix\ext RECNO 883

ASTM F 1541 CLASSIFICATION OF THE Xxxxxxxx EXTERNAL FIXATION SYSTEM

The following is a list of descriptors defined in ASTM F 1541 to aid in identifying and classifying this external fixation system. Because this device was cleared in a previous 510k, this review memo only describes in detail components which are new to this system, i.e., the 2 wires and the washer (identified by * below).

Overall system
- Fixator-Bone Construct Classification
  - Long bone
  - Limb lengthening
- Frame limb access
  - Multilateral
    - Ring fixator
      - Circular
- Frame pin configuration
  - One-plane

Anchorage elements
- Wire-fixed
  - Wires
    - Smooth*
    - Olive*
- Washer*

Bridge elements
- Complex

Connectors
- Non-adjustable joints

DESCRIPTION OF EACH COMPONENT UNDER REVIEW IN THIS 510K

COMPONENT 1 washer

MATERIAL	Ti-6Al-4V	STANDARD #	ISO 5832-3
INTERFACES	ARTICULATIONS none	MATING PARTS	olive wire
	TISSUE FIXATION bone	COATINGS	anodization
DESIGN	7 mm OD. Distributes the load applied by the olive wire over a greater area of the bone.		

COMPONENT 2 olive wire

MATERIAL	Ti-6Al-4V	STANDARD #	ISO 5832-3
INTERFACES	ARTICULATIONS none	MATING PARTS	washer, frame
	TISSUE FIXATION bone	COATINGS	anodization
DESIGN	1.8 x 400 mm. Creates interfragmentary compression and adds greater stability.		

COMPONENT 3 smooth wire

MATERIAL	Ti-6Al-4V	STANDARD #	ISO 5832-3
INTERFACES	ARTICULATIONS none	MATING PARTS	frame
	TISSUE FIXATION bone	COATINGS	anodization
DESIGN	1.8 x 400 mm. Creates interfragmentary compression and adds greater stability.		

COMPONENT 4 anodized coating
STANDARD # xxxxxx SEE ALSO Kxxxxxx
DESIGN This blue oxide coating allows the Ti alloy parts to be distinguished from SS parts.

COMPARABLE PREDICATE DEVICES

As required by 21 CFR 807.87 (f), the device under review in this 510k is compared for substantial equivalence to a legally marketed predicate device which was found to be substantially equivalent in a 510k (predicate device), viz., Kxxxxxx Xxxxxxxx External Fixation System: components 1-3 described above but made of 316 LVM SS.

The differences in the design (compared to predicate devices) do not raise new types of safety and effectiveness questions (risks) not seen before in similar devices. The same risks occur in both devices.

TECHNOLOGICAL CHARACTERISTICS:

Possible clinical complications/risks for the device under review may include the following:

1. pin-tract infection,
2. ring sequestrae,
3. prolonged healing,
4. distraction of the fracture site,
5. delayed or non-union,
6. bone fracture.

Non-union of the original fracture and resorption of bone after fracture fixation often initiate these complications so the external fixator submitted in this 510k was evaluated to determine the likelihood of non-union or bone resorption by the following tests:

RIGIDITY (OR DEFLECTION) MEASUREMENTS

Xsss, X.; Yyyyyyyyy, Y. 1996 measured the stiffness of the external fixator wires to determine the clinical significance of differences in materials. Testing was conducted at Zzzzzzzz 01/96. The 10 test samples were Ti-6Al-4V 1.8 mm wire under a tension of xx or yyy Kg. The 10 control samples were SS with the same characteristics. Samples were loaded normal to the wire axis in a pseudo 3 point bending at x mm/min at the center of the wire. Each sample was loaded x times and the final rigidity used in comparisons. The rigidity of the test and control samples was xx +- x.x and yy +- y.y N/mm respectively. The z% difference in stiffness between the two types of wire was not significant.

STATIC FAILURE OF THE DEVICE

This testing determines the static load to failure of the entire construct. Xxxxx, X.; Yyyyyyyyy, Y. 1994 (page 4) measured the strength of external fixator wire. Samples were loaded in parallel to the wire axis in tension at x mm/min. The results for the Ti test and SS control samples were xxxx and yyyy N

respectively. The SD was xxx and yy N respectively, so the Ti wire load to failure was significantly below that of the SS wire. The lower Ti wire strength may not be a problem for two reasons:

Even the xxxx N failure load of the Ti alloy wire exceeds 3 times body weight (2000 N) by 900 N, i.e., yy% of xxxx N.

More than one wire is used in parallel, so the load is shared.

FATIGUE FAILURE AND LOOSENING BETWEEN PARTS

Xxxxx, X.; Yyyyyyyyy, Y. 1994 (page 4) evaluated the cyclic fatigue strength of external fixator wire. Samples were loaded normal to the wire axis in 3 point bending at xx-yyy N (z Hz) at the center of wire until failure. Failure of the Ti test and SS control samples occurred after xxxxx and yyyyy cycles respectively for the 1.8 mm wires. The difference was not significant.

THERMAL NECROSIS DUE TO DRILLING THE WIRE THROUGH THE BONE

Xxxxx, X.; Yyyyyyyyy, Y. 1994 (page 4) measured bone temperatures during drilling of external fixation wire through simulated bone (Last-A-Foam) to determine any differences in results due to differences in materials. Testing was conducted at Zzzzzzzz 05/01/94. Samples were loaded xx N during drilling along the wire axis. The Ti wire and SS wire heated the bone model to xx and yy C, but the SD was around x and y C respectively, so there was no significant difference.

Differences between the two materials may have made a difference in the amount of heat generated if lubricant or real bone were used. Therefore, I do not feel this test accurately determines any differences between the SS and Ti wires. The actual temperatures should be lower if lubricant is used, but the effect of not using real bone is unknown. This test is not critical to safety and effectiveness, so I do not recommend requesting further information.

SUMMARY OF INFORMATION SUPPORTING DECISION/RECOMMENDATION:

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

REVIEWED BY: _____

Xxx Xxxxxxxxx

ATTACHMENTS:

design drawings, photos, predicate device, intended use statement

CONTACT HISTORY:

The following is a chronological listing of all requests for information made by Xxx Yyyyyy to the firm regarding this 510k, followed by a summary of the firm's response in their next correspondence (the firm's response is indented below each request):

As per 21 CFR 807.87(h), I advised Xxx Xxxxx 7-29-96, 2 pm that there was insufficient information to make a determination concerning substantial equivalence. I then requested the following information:

1. The Ti wire load to failure was significantly below that of the SS wire. Discuss the effect of this on clinical outcomes.

FDA received an adequate response to this request.

2. Provide information on differences in fixator rigidity using SS versus Ti wire. The device under review is made out of a material with a lower modulus compared to the predicate, which may result in a lower rigidity. Rigidity affects bone resorption and union of the fracture. Too little rigidity may lead to instability and nonunion.

FDA received an adequate response to this request.

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