REVIEWERS GUIDANCE CHECKLIST FOR INTRAMEDULLARY RODS

Version #4

CONTENTS

APPENDICES

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. Compare the intended use of the new device to the predicate(s). Intramedullary rods are generally rod shaped devices with or without screw holes at either end for fixation to bone. These class II devices are defined in 21 CFR 888.3020 as "a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures" (product code 87HSB). Any other intended uses should be removed from the labeling or supported by clinical data. Some designs of IM rods may be used in a variety

of bones, while other designs are site specific (e.g. tibia). The site of application of the predicate device(s) should be consistent with the intended use of the new device.

2. Certain intramedullary rods may require more analysis than is covered in this document. Examples of such devices might include a rod with a lower rigidity, rods that are adjustable in length after implantation, or magnetic alignment of bone screws to attach a rod. Such devices which involve new and/or complex issues will not be reviewed by third parties because special analysis of the risks and mechanical and/or animal testing may be necessary which is beyond the scope of this document.

3. Describe the device as outlined in appendices 1, 2 and 3.

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

1. Compare the intended uses, design, materials, properties, methods of fixation, 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 intramedullary rods as well as based on what has been previously cleared by FDA. Common complications involving intramedullary rods include: loss of alignment, distraction of the fracture, infection, limb shortening, migration, muscle atrophy, non-union, protrusion through cortex, loss of range of motion, vascularity effects due to rod dimensions/geometry.

3. Identify the potential benefits of the new device compared to the 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, 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. Intramedullary rods are generally made out of medical grade CoCrMo, Ti-6Al-4V or 316 LVM stainless steel. Materials or combinations of materials with limited or no history of safe use as orthopedic implants should demonstrate a biological response at least as good as a predicate or substantially equivalent device when tested, e.g., according to the ISO 10993 for Medical Devices and in an appropriate animal study.

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

4. 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.

5. 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 4).

Appendix 1. The description of the rod under review and the predicate device should include the following (see ASTM F1264-96):

lengths

longitudinal curvature

diameter

inner (if not solid)

outer

thickness

cross sectional shape (e.g., circular, fluting, open, closed, slotted, width of opening)

fixation mechanism (e.g., interference, elastic deformation of the device, bone screws)

number of fixation points

orientation of the open section and other asymmetries in the sagittal and coronal planes (e.g.: curved, bent ends, straight, s-shaped, stepped)

potential critical stress concentrators

number to be implanted

design of ends (e.g., flat, pointed, blunt, threaded, round)

insertion/extraction mechanism

Appendix 2. Standards which may be consulted include the following:

ASTM F-339:	Standard Specification for Cloverleaf Intramedullary Pins
ASTM F-453:	Specification for Hooked Intramedullary Pins
ASTM F-454:	Specification for Intramedullary Pins
ASTM F-455:	Specification for Intramedullary Nails with a Solid Cross-section
ASTM F-1264:	Standard Guide for Mechanical Performance Considerations for Intramedullary Fixation Devices
ISO 5837-1:	Implants for Surgery - Intramedullary Nailing Systems - Part 1: Intramedullary Nails with Cloverleaf or V-shaped
ISO 5537-2	Implants for Surgery - Intramedullary Nailing Systems - Part 2: Medullary Pins

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 assembled construct, indicating the proximal and distal attachment mechanisms and indicating if the attachments are to cortical or cancellous bone

drawing showing where the part 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

Appendix 5. Bibliography

Test standards for intramedullary rods include the following:

ASTM F-383: Practice for Static Bend and Torsion Testing of Intramedullary Rods

ASTM F-1264: Standard Guide for Mechanical Performance Considerations for Intramedullary Fixation Devices

Draft ASTM Standard Definitions of Terms for Sizing of Intramedullary Fixation Devices (IMFD's) and Associated Instrumentation

Draft ASTM Standard Practice for Measuring Intramedullary Fixation Devices (IMFD's) and Reamer Dimensions

Draft ASTM Standard Practice for Low Cycle Intrinsic Bending Fatigue Testing of Intramedullary Fixation Devices (IMFD's)

Draft ASTM Standard Practice for Static Testing Under Combined Axial Compression and Bending Loads for Proximal and Distal Cortical Locking Mechanisms of Intramedullary Fixation Devices (IMFD's)

Draft ASTM Standard Practice for Low Cycle Fatigue Testing Under Combined Axial Compression and Bending Loads for Proximal and Distal Cortical Locking Mechanisms of Intramedullary Fixation Devices (IMFD's)

Draft ASTM Standard Practice for Static Intrinsic Bending, Torsion, and Radial Compliance Testing of Intramedullary Fixation Devices (IMFD's)

Appendix 6. Sample review memo of an external fixation system

im flexi met ti 64 screw

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

DATE February 21, 1997
FROM KEN MCDERMOTT
TO File

DOCUMENT # Kxxxxxx
SPONSOR Xxxxxx
DEVICE NAME Xxxxxxx Nail

CLASS HSB
DISEASE/USE fracture of the humerus

REASON FOR APPLICATION New device.

DECISION SE The most important factors affecting this decision include the following:

1. The intended use of the above referenced device and predicate devices are essentially the same.

2 The design of the above referenced device and predicate devices are similar except for small differences that should not affect safety and effectiveness.

DESCRIPTION OF EACH COMPONENT UNDER REVIEW IN THIS 510K

COMPONENT 1	4 mm interlocking screw		
MATERIALS	Ti-6Al-4V	STANDARD #	ASTM F 136
INTERFACES	ARTICULATIONS none	MATING PARTS IM rod	
	TISSUE FIXATION bone	COATINGS none	
COMPONENT 2	IM rod		
MATERIALS	Ti-6Al-4V	STANDARD #	ASTM F 136
INTERFACES	ARTICULATIONS none	MATING PARTS screw	
	TISSUE FIXATION none	COATINGS none	

ROD DESIGN FEATURES
straight
lengths: 200-300 mm
solid
diameter: 8 mm
cross sectional shape: oval
fixation methods: 2 bone screws
asymmetries: wide at one end,
tapering at the other
a single rod is implanted in the canal
design of ends
flat at the wide end with holes
blunt at the tapered end
STERILITY gamma radiation
FILE bonfix/im

COMPARABLE PREDICATE DEVICES

PREDICATE DEVICE I REVIEWED RECENTLY

DOCUMENT #	Kxxxxxx		
SPONSOR	Xxxxxxxxxx		
DEVICE NAME	Xxxxxx Intramedullary Rod System		
CLASS	HSB		
DISEASE/USE	Fracture of the proximal humerus		
REASON FOR APPLICATION	New device.		
DECISION	SE This device has equivalent intended use, conforms to similar standards, and has equivalent technological characteristics compared to predicate devices.		
COMPONENT 1	IM rod		
MATERIALS	Ti-6Al-4V	STANDARD #	ISO 11137
INTERFACES	ARTICULATIONS none	MATING PARTS capscrew	
	TISSUE FIXATION none	COATINGS none	

length: 155 mm
straight
diameter : 9-15 mm
solid
circular cross sectional shape
10 flutes and 3 slots run from the distal end to the screw holes.
fixation method: interference or bone screws
number of fixation points: proximally (at the humeral head) there are 4 screw holes and 4 suture holes.
a single rod is implanted in the canal
blunt distal end
flat proximal end with threaded insertion/extraction hole

COMPONENT 2	xxxxxxxx		
MATERIALS	Ti-6Al-4V	STANDARD #	ISO 11137
INTERFACES	ARTICULATIONS none	MATING PARTS IM rod	
	TISSUE FIXATION none	COATINGS none	
DESIGN	Prevents tissue from entering threaded hole which attaches to insertion/extraction instrumentation.		

OTHER PREDICATE DEVICES (see attached)

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:

There are no important differences between the device submitted in this 510k and similar devices which would require testing. A 510(k) indications for use statement, truthful and accuracy statement and summary of safety and effectiveness were submitted as required in the Safe Medical Devices Act.

REVIEWED BY: _____
Xxx Xxxxxxxxx

ATTACHMENTS:

design drawings
predicate device
intended use statement

CONTACT HISTORY: None