GUIDANCE DOCUMENT FOR FEMORAL STEM PROSTHESES

DRAFT

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PLEASE FORWARD YOUR COMMENTS TO:

Orthopedic Devices Branch

Division of General and Restorative Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration

9200 Corporate Blvd.
Rockville, MD 20850

301-594-2036

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MATERIAL AND DESIGN DESCRIPTION

list each part of each component of the total hip system including:

1. the name of the component and each its parts
2. types of interfaces, e.g.:
   a. articulating
   b. fixed mating part
   c. coating
   d. tissue fixation
3. the material composition of each component, including:
   a. previous submissions to FDA or other references
   b. voluntary standards and any deviations
   c. any trade names for the material
   d. establishments which process the material
4. major processing methods
5. roughnesses of all surfaces
6. details about the design

EVALUATION OF SURFACE TREATMENTS

EVALUATION OF CALCIUM PHOSPHATE (Ca-P) COATINGS

EVALUATION OF CERAMIC BALL HIP SYSTEMS

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FATIGUE PROPERTIES

A STEM DOES NOT HAVE TO BE FATIGUE TESTED IF:

1. the predicate stem has passed the fatigue testing outlined below
2. data demonstrates design differences have no affect on fatigue properties

GENERAL TEST METHODS

1. follow ISO 7206-3 (without torsion) or 7206-4 (with torsion)
2. use finished product, acceptable for clinical use
3. stems must have worst case dimensions and tolerances
4. potting medium
   a. composition (preferably bone cement)
   b. methods of stem embedding
5. potting level must be a minimum 80 mm +- 2 mm from the center of the head and the stem diameter at the potting level
6. initial lateral head deflection under maximum load

ADDITIONAL TEST REQUIREMENTS (CHOOSE AT LEAST ONE)

FATIGUE STRENGTH (7206-7 (without torsion) or 7206-8 (with torsion))

1. test at least six devices (none should fail below $5x10^6$ cycles)
2. the maximum test load shall equal or exceed that specified in 7206-7 or 7206-8

FATIGUE STRENGTH LESS THAN THAT SPECIFIED IN 7206-7 OR 7206-8, BUT EQUAL TO OR BETTER THAN A CONTROL AND PROVIDE CLINICAL DATA

1. the control device and the new device must be similar in:
   - size
   - material composition
   - general design
   - method of fixation
   - location of surface modifications
2. determine fatigue limit ($\geq 10^6$ cycles) of the new device and the control using statistically valid sample sizes
3. loads must produce failures at about $5x10^6$ cycles (i.e., test until failure)
4. clinical data addressing stem fracture for either the control device or the new device

CONTRAINDICATED WEIGHT LIMIT(S)

1. six devices must be tested, all surviving $5x10^6$ cycles
2. provide test data for each size
3. maximum test load (R = 0.1) 3 times the maximum patient body weight recommended on the labelling
4. labelling by contraindication as not for use in patients above a certain weight

ALTERNATIVE FATIGUE TESTING

validate alternative fatigue test for:

unusual stem designs or sizes
new stem designs with different failure mechanisms

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PREFACE

The purpose of this document is to recommend to the device manufacturer or sponsor of premarket notifications (510(k)), Investigational Device Exemption (IDE), Premarket Approval (PMA), reclassification petition, or master file important information that should be submitted to FDA in order for FDA to determine the substantial equivalence and/or safety and effectiveness of femoral hip stem protheses. This information includes important issues and concerns, properties that should be evaluated, summaries of possible test methods, rationale/purpose of each test, pass/fail criteria or typical results for each test, literature citations, and a format for organizing data for submission to FDA.

The development of this guidance document is based on an evaluation of the literature and on the experience of the Orthopedic and Rehabilitation Devices Branch (ORDB) and is primarily intended to be a scientific position paper. Therefore, it suggests some important evaluation criteria, test procedures, and end points that FDA feels are necessary to provide reasonable assurance of substantial equivalence and/or safety and effectiveness of femoral stem prostheses. Although this guidance document contains certain administrative requirements, it does not replace the requirements of the 21 CFR 801 or 807 or the statue.

FDA may require information in addition to what is contained in this document if circumstances require it. In other instances, the sponsor may be able to sufficiently justify the omission of some tests. Suggestions and recommendations presented in this document are not mandatory requirements, but reflect data and methodologies which ORDB has determined to be acceptable. Therefore, the words "should", "must" and "shall" are not used in a regulatory sense and should not be construed as such. They express FDA's current feeling as to what constitutes good scientific decision making.

The guidance document should be viewed as a living document. As scientific knowledge changes and scientific techniques are improved, FDA will revise the document. Nonetheless, the basic objectives will remain the same.

MATERIAL AND DESIGN DESCRIPTION

Each part of each component of the total hip system should be listed along with the following information:

1. the name of the component and each of its parts;
2. a description of all types of interfaces, e.g., articulating, fixed mating part, coating, tissue fixation);
3. the material composition of the component to include:
    a. the reference number of any previous submission to FDA or other reference which more fully characterized the material (e.g., master file, 510k, literature article);
    b. a brief description of the material or the name and number of the voluntary standards that applies to the material (any difference in the final product and the requirements in the referenced standard must be itemized and justified);

c. any trade names for the material; and

d. establishments which process the material.

4. the major processing methods which determine the material microstructure, and hence, its properties;

5. roughnesses of all surfaces; and

6. details about the design (e.g., engineering drawings, model numbers, sizes, photographs, purposes) and a description of the function of each major design feature (examples are given in APPENDIX 1: PARTS/COMPONENTS AND THEIR MAJOR DESIGN FEATURES).

EVALUATION OF SURFACE TREATMENTS

See the "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement".

EVALUATION OF CALCIUM PHOSPHATE (Ca-P) COATINGS

See the "Calcium Phosphate (Ca-P) Coatings Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants".

EVALUATION OF CERAMIC BALL HIP SYSTEMS

See the "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems".

ARTICULATING WEAR

See the "Guidance Document for Testing Acetabular Cup Prostheses".

FRETTING AND CORROSION BETWEEN PARTS

Fretting and/or corrosion testing may be necessary for a stem which has the same design as a predicate stem except for differences in features which may affect fretting and/or corrosion between parts or if the predicate design has problems in these areas. To evaluate these properties, see the "Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components".

FATIGUE PROPERTIES

STEMS WHICH DO NOT REQUIRE FATIGUE TESTING

Fatigue testing must be conducted to demonstrate that the device will continue to function without fracture in the intended patient population for an acceptable period of time. A stem which has the same design as a predicate stem except for differences in features which do not affect the stem's fatigue strength (e.g., cone taper) does not require fatigue testing provided the predicate stem has passed the fatigue testing outlined below. Data (e.g., stress analysis) may also be necessary to demonstrate that the differences between the predicate and the new stem design probably have no effect on the stem fatigue properties.

GENERAL TEST METHODS

1. Testing must be in accordance with the methods of ISO 7206-3 (without torsion) or 7206-4 (with torsion), except as clarified and modified below.

2. All test samples must be finished product, acceptable for clinical use.

3. The stem dimensions and tolerances that would be expected to produce the most highly stressed components and greatest damage (i.e., worst case) must be tested.

4. The potting medium composition (preferably bone cement or a material which is mechanically similar) and the methods of stem embedding must be reported.

5. The potting level must be a minimum 80 mm +- 2 mm from the center of the head. The stem diameter at the potting level must be reported.

6. Lateral head deflection under maximum load should be measured at the initiation of each test to provide an indication of the moment arm and thus stress applied to the specimen.

7. In addition, at least one of the following test requirements must be adopted:

OTHER TEST REQUIREMENTS (CHOOSE AT LEAST ONE)

FATIGUE STRENGTH (7206-7 (without torsion) OR 7206-8 (with torsion))

1. A minimum of six devices must be tested. All should survive $5x10^6$ cycles without failure.

2. The maximum test load shall equal or exceed that specified in 7206-7 or 7206-8.

FATIGUE STRENGTH LESS THAN THAT SPECIFIED IN 7206-7 OR 7206-8, BUT EQUAL TO OR BETTER THAN A CONTROL AND PROVIDE CLINICAL DATA

1. The control device and the new device must be similar in:

   size,

   material composition,

   general design,

   method of fixation (biologic, cement, press fit), and

   location of surface modifications (e.g. proximal porous coating).

2. Statistically valid sample sizes should be used to demonstrate that the fatigue limit at a minimum of 10^6 cycles for the new device is no worse than that of the control.

3. Loads for both the test device and the control should be chosen to produce failures at about $5x10^6$ cycles (i.e., continue the test until failure occurs).

4. Data on the clinical performance with respect to stem fracture must be provided for either the control device or the new device.

CONTRAINDICATED WEIGHT LIMIT(S)

1. A minimum of six devices must be tested. All should survive $5x10^6$ cycles without failure.

2. If different weights are suggested for different sizes, test data for each size must be submitted.

3. The maximum test load (R = 0.1) shall be 3 times the maximum recommended (on the labelling) patient body weight for the stem tested.

4. The device must be labelled, by contraindication, as not for use in patients above a certain weight. The contraindicated weight limit(s) may be size-specific.

ADDITIONAL TESTING

Unusual stem designs (e.g., long distal slot) or sizes (e.g., extra long stems) may require additional testing (e.g., static three point bend test) if the clinical loading profile of the new stem may differ significantly from that of stems for which the ISO standards were designed. Stress analyses and/or mechanical bench testing may be needed to validate the test model.

New stem designs (e.g., polymer composites) which fail at a load and/or number of cycles below what is described above due to new failure mechanisms, may be tested by other methods provided there is adequate clinical evidence, stress analyses and mechanical bench testing which:

1. justifies the load configurations and validates the test model, and which

2. demonstrates that the clinical failure mechanisms of the new stem (e.g., delamination, creep, shear failure, crazing or chemical attack of polymer composite stems) would substantially deviate from failure mechanisms that would result if tested by ISO 7206-3 or 7206-4 (i.e., fatigue crack in the distal shaft).

REPORTING

Test reports which omit information, or are not organized the same way by each investigator, makes FDA's review more difficult and delays determinations of substantial equivalence and/or safety and effectiveness. To facilitate FDA's review, detailed reports should include the information which is organized and subdivided into separate sections (some sections may be combined to enhance clarification) as outlined in Appendix 2.

APPENDIX 1: PARTS/COMPONENTS AND THEIR MAJOR DESIGN FEATURES

MODULAR PARTS/COMPONENTS	MAJOR DESIGN FEATURES
	ACETABULAR CUP
BACKING	SCREW HOLE DOME HOLE
ARTICULATING INSERT	SUBLUXATION LIP (DEGREES) BC FLANGE ECCENTRICITY (OFFSET) CONSTRAINT CAPTURED BALL FULLY-CONSTRAINED NONCONSTRAINED SEMI-CONSTRAINED
LINER	
LOCKING RING	
RADIOPAQUE MARKER	
CEMENT SPACER	
	BALL (HEAD) PARTS
BORE INSERT	
BIPOLAR INSERT	
	FEMORAL COMPONENT
STEM CENTRALIZER BONE CEMENT PLUG EXTENDER	
SHAFT	GENERAL: CROSS-SECTION: ROUND/OVAL HANDEDNESS: LEFT/RIGHT STRAIGHT OR CURVED TAPERED
COLLAR	DISTAL: COLLAR FLUTED SLOT (CLOTHS PIN) PROXIMAL: EXTRACTION HOLE FENESTRATION
SLEEVE CEMENT SPACER	
OTHER	SPECIFIC STYLE (SEE ASTM F 370)

MODULAR PARTS/COMPONENTS

MAJOR DESIGN FEATURES

FIXATION MECHANISMS: COMPONENT-TO-TISSUE & COMPONENT-TO-COMPONENT

ADHESIVE
BOLT OR SET SCREW
BONE SCREW
    CORTICAL
    CANCELLOUS
COATING
    CALCIUM PHOSPHATE CERAMIC
    METAL
        PLASMA SPRAYED
        POROUS SINTERED
    NORMALIZED
SURFACE
    ROUGHENED
    SMOOTH
    TEXTURED
    MORSE TAPER
OTHER
    WELDED

    BONE CEMENT
    PEG OR PIN

APPENDIX 2: TEST REPORT CONTENT

Detailed reports should be organized and subdivided into separate sections (some sections may be combined to enhance clarification) having (if applicable) the following headings:

1. Report title
2. Investigators' names
3. Facility Performing the test
    - Name
    - Address
    - Phone Number
4. Dates
    - Test initiation
    - Test completion
    - Final report completion
5. Objectives/Hypothesis
6. Test and control samples
    - Sample selection criterion
    - Design
    - Materials
    - Processing methods
    - Differences between test samples, control samples and marketed device
7. Methods and Materials
    - Test setup schematic or photograph
    - List dependent, independent and uncontrolled variables, i.e.:
        - Test and control sample parameters
        - Environment composition, pH, volume, flow, temperature, replacement
        - Load directions, points of application and magnitudes
        - Times (e.g. rates, frequencies, number of cycles)
        - Other
    - Rationale for choices of parameters, values, etc.
    - Methods of specimen examination
    - Statistical justification for the number of samples
    - Chronological description of the test procedures
    - Deviations from referenced protocols and standards
8. Results
    - Potting medium composition and processing methods
    - Time till the embedding medium asymptotically reaches its maximum strength
    - Time from mixing the embedding medium till cyclic loading commences
    - Strength of the embedding medium after cyclic loading
    - Offset angle
    - Head offset length
    - Loading frequency
    - Lateral head deflection of each sample
    - Cracking, deformation and creep of the embedding medium for each specimen
    - Stem failure load
    - Stem failure analysis
    - Discussion of the data and possible mechanisms
9. Conclusions
    - List of conclusions
    - Discussion of the objective/hypothesis
    - Simplifications and assumptions made and clinical implications of results
10. Appendices
    - Experimental data
    - Calculations
    - Bibliography of all references pertinent to the report

ORDER: hip COMPONENT SUBPART FIXATION MATL

COMPONENT: BIPOLAR ACE backing liner BALL FEM collar cone shaft part sleeve HEMI SAP

FIXATION: porous cap

MATL: cer alox zir met cocr ss ti ASTM F 1440, Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion.

ASTM Standard Practice for The Determination of the Cyclic Fatigue Strength of Modular Self-Locking Femoral Heads in Hip Arthroplasty (task force F04.03.02.14)

ASTM Standard Practice for: Flexural Fatigue Testing of Metallic Taper Lock Modular Distal Component of Hip Prostheses

ASTM Standard Test Method for Torsional Fatigue/ Micromotion Testing of Modular Acetabular Components

The following samples must be tested:

A. 1 sample loaded to failure in 1 cycle to obtain the static yield load;

B. 2 samples cyclically loaded at 75% of the static yield load till failure or 5×10^6 cycles;

C. 2 samples cyclically loaded at 50% of the static yield load till failure or 5×10^6 cycles; and

D. 2 samples cyclically loaded at 25% of the static yield load till failure or 5×10^6 cycles.

5. The load versus number of cycles must be plotted to estimate the endurance limit.

with design features (e.g., new material, smaller dimensions, grooves, sharp corners, porous coatings) which may lower the fatigue strength vis a vis predicate stems.

STRENGTH

ASTM Standard Practice for: Measurement of the Static Locking Force of Modular Proximal Bodies in Hip Prostheses

ASTM Standard Test Method for Static Evaluation of Liner Locking Mechanism - Torque Test

ASTM Standard Test Method for Static Evaluation of Liner Locking Mechanism - Push Out Test

A stress analysis with a laboratory test to backup the data, may be conducted to estimate critical loading points

WEAR

ASTM F 732, Standard Practice for Reciprocating Pin-on-Flat Evaluation of Friction and Wear Properties of Polymeric Materials for Use in Total Joint Prostheses

ASTM Practice for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices

FLEXIBLE STEMS

The ISO 7206-4 femoral fatigue test method evaluates failure mechanisms involving cement breakdown, leading to bone regression, resulting in a lack of proximal support and eventual stem fatigue fracture. This may not be appropriate for low rigidity stems (e.g., made out of a polymer composite) for two reasons:

1. Flexible stems should apply greater loads against the bone so proximal bone loss is less likely.

2. Unlike metal stems, polymer composite stems are mechanically anisotropic and fail due to delamination, creep, shear, crazing and chemical attack.

Therefore, failure mechanisms of a composite stem tested by the ISO method could substantially deviate from in vivo failure mechanisms. Methods other than ISO 7206-4 may be used provided there is adequate clinical and mechanical evidence justifying the load configurations.

For example, Humphrey, S.M.; Gilbertson, L.N.: ('Fatigue Testing of Femoral Hip Prostheses with a Two-Beam Simulated Femoral Bone Support Fixture'. Jamison, R.D.; Gilbertson, L.N. (editor): Composite Materials for Implant Applications in the Human Body, ASTM (pub.), pp. 27-40, 1993) developed and evaluated a method of measuring composite stem fatigue properties under realistic loading conditions involving partial proximal support. A specific stem size was fixed at a 15 degree angle between the femoral and load axes in the M-L plane and at a 10 degree angle in the A-P plane using bone cement. The distal 38.1 mm of the stem was rigidly fixed in bone cement.

The proximal part of the stem was also potted in cement and held by a cantilever beam which allowed some deflection of the proximal part of the stem. The material and dimensions of the fixture support beams were chosen based on FEA so the fixture simulated the stiffness of bone produce clinically realistic stem deflections. The stem was also implanted in a composite bone in the same orientation. The strains and deflections of the stem under static loading in the fatigue test fixture and in the composite bone were comparable and the fixture accurately simulated expected in vivo loading.

STEMS WITH A DISTAL SLOT

Hip stems with a distal slot must be cyclically fatigue tested by loading normal to the slot. Results must be compared to a legally marketed device with similar design and dimensions.

CLINICAL DATA ON NEW STEM

Prospective clinical data may be gathered on the new device under an approved IDE. Followup under the IDE must be for at least 3 years on a statistically-valid population, with x-ray verification of freedom from complete or partial fracture at 3 years.

INFORMATION ON Hz: see Farhangi & 25993-5