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.

DATA REQUIREMENTS FOR ULTRAHIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE) USED IN ORTHOPEDIC DEVICES

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I. INTRODUCTION

The purpose of this document is to list the data needed for orthopedic devices containing UHMWPE. These data should be included in premarket notifications (510k), Investigational Device Exemptions (IDE) applications, Premarket Approval (PMA) applications, reclassification petitions, and master files to aid FDA in determining the substantial equivalence and/or safety and effectiveness of UHMWPE in implantable orthopedic devices. In this document UHMWPE is referred to as polyethylene (PE).

For specific applications, FDA may require information in addition to that outlined in this document. In other instances, data requirements in this document may be omitted with sufficient justification. Suggestions and recommendations presented in this document are not mandatory requirements and the words "should", "must" and "shall" are not used in a regulatory sense and should not be construed as such.

FDA may periodically update this document to reflect modifications in the data requirements for evaluating PE.

II. TEST REQUIREMENTS

All submissions with PE components must provide the data in Stage 1 below. If the PE is similar to PE on the market, no further material data are required. However, additional design specific testing, such as surface contact stresses, may be needed. If the data from Stage 1 demonstrates that the PE differs from PE on the market, additional Stage 2 data may be required. Which Stage 2 data are needed will be determined for each individual submission. For example, any claims for the PE must be substantiated. Stage 3 data may be required if the Stage 1 and Stage 2 data show the new material to be significantly different than other PE components. Stage 3 is also required if the chemical composition of the product differs from ASTM F 648: UHMWPE Powder and Fabricated Form for Surgical Implants. Note: all testing must be performed on the final, sterilized material.

<u>Stage 1</u> Mechanical Properties:

- Ultimate Tensile Strength
- Yield Strength
- Young's Modulus (Modulus of Elasticity)
- Poisson's Ratio
- % Elongation

Other Properties

- Molecular Weight
- Density and Porosity
- Crystallinity
- Glass Transition Temperature, T_g
- Crystallization Temperature Range, T_c
- Melting Temperature, T_m
- Oxidation Temperature, T_o

Stage 2 Mechanical Tests:

- Creep
- Wear
- Fatigue
- Crack Propagation
- J Integral,

Other Tests:

- Thin Sectioned Photomicrograph
- IR Spectra and Chemical Structure

Stage 3 Clinical Data
Biocompatibility

It is up to the investigator to determine which initial tests are necessary in stages II and III. The tests should report the storage time and test environment.

III. CONTROLS

Li and Howard ("Characterization and Description of an Enhanced Ultra High Molecular Weight Polyethylene for Orthopaedic Bearing Surfaces." Transactions of the 16th Annual Meeting of the Society of Biomaterials, p. 190, May, 1990) have demonstrated that significant property variations occur between the four sources of PE in the world, the different grades of PE and different PE lots. Wright, T.M. ("Polyethylene: Mechanisms of Wear and Enhanced Forms." The Hip Society 20th Open Scientific Meeting at the AAOS, p. 26, February, 1992) reported that testing of various PE implant components produced differences in creep properties of 400% and differences in ductility of 111% Therefore, the PE must be compared to a legally marketed PE that has been clinically successful under similar physiologic loading conditions.

IV. REPORTING

To help FDA evaluate the substantial equivalence and/or safety and effectiveness of new PE components, submitted test reports should contain the information listed below.

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 and control samples and marketed device

7. Methods and Materials
    - Test setup schematic or photograph
    - Description of grips or potting medium interfacing with samples
    - List of dependent, independent and uncontrolled variables, i.e.:
        - Test and control sample parameters
        - Environment composition, pH, volume, flow, temperature
        - Electromagnetic fields, applied charges, irradiation
        - Load directions, points of application and magnitudes
        - Times (e.g. rates, frequencies, number of cycles)
    - Methods of specimen examination (e.g., failure analysis)
    - Chronological description of the test procedures
    - Deviations from referenced protocols and standards

8. Results
    - Time from manufacturing until commencement of testing
    - Discussion of the data
    - Conclusions, including statistical analysis
    - Discussion of the objective/hypothesis
    - Clinical implications of results (including a discussion of assumptions)

9. Appendices
    - Experimental data
    - Calculations
    - Bibliography of all references pertinent to the report

The following voluntary standards may be useful in preparing data outlined in this document:

- ASTM D 621: Standard Test Methods for Deformation of Plastics Under Load.
- ASTM D 638: Standard Test Methods for Tensile Properties of Plastics
- ASTM D 671: Standard Test Methods for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force.