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.

510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants

March 10, 1995 (revised 2/20/97)

1. the particle size and the particle size distribution of metal and HA powders used for coating, the average porosity size, the overall pore volume and the total surface area of the implantable portion of the coated implant;

2. scanning electron microscopy pictures of the metal particle- and the HA-coated implant surfaces as well as the cross-sectioned area of the device including measurements of the coating thickness and tolerances;

3. chemical analysis of HA powders before and after coating, including Ca/P ratios, elemental analysis, etc. A sufficient number of samples should be analyzed to produce a statistically meaningful mean and variance;

4. bonding strength between HA and titanium alloy or metal with standard deviation analysis including at least ten samples. The detailed testing protocol and the methods for sample preparation should be provided;

5. the solubility products of HA particles before and after coating (i.e., scraped HA particles from coated implant) measured at 37^oC. Room temperature and 100^oC measurements are optional. The pH changes of the solutions should be recorded. The solubility products (K_{sp}) should be calculated based on HA, $Ca_{10}(PO_4)_6(OH)_2$ formulation;

6. dissolution rate of HA particles before and after coating (i.e., scraped particles with controlled particle size and surface area) measured at 37^oC in a pH 7.3, buffered solution. The activation energy and the Arrhenius constant of the dissolution reaction are optional. The possible pH changes of the solution should be recorded;

7. x-ray diffraction patterns of HA before and after coating and of scraped HA from coated samples with crystallographic interpretations, including the identification and the quantitative analysis of each crystalline and amorphous phase, degree of crystallinity and perfection of HA crystals, preferred orientations, effect of strain and/or particle size, etc. The analysis should be performed with a Cu/Kα radiation and scanned from 4^o to 60^o;

8. infrared spectra of HA before and after coating and of scraped HA from coated samples with detailed molecular interpretations, including band assignments, perfection of HA crystals, structural water and carbonate, etc.;

9. detailed process(es) (i.e., either annealing or solution treatments) for improving the HA crystallinity and purity after coating;

10. detailed, tabulated comparison, including size, geometry, materials used, surface and bulk properties, processes of coatings, etc. between devices that your company intends to distribute in the United States and the U.S. legally marketed devices to which you are claiming to be substantially equivalent.