

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.

TENTATIVE

Attachment A

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4-Of-A-Kind PMAs

ORTHOPEDIC DEVICES PANEL

- \*Bone Cement
- \*Bone Growth Stimulator System for Long Bone Nonunions  
Biologically Fixed Hip Prosthesis

GENERAL AND PLASTIC SURGERY DEVICES PANEL

- Absorbable Powder for Lubricating a Surgeon's Glove (878.4480)
- \*Absorbable Hemostatic Agent and Dressing (878.4490)
- \*Absorbable and Nonabsorbable Surgical Sutures

GASTROENTEROLOGY/UROLOGY DEVICES PANEL

- \*Therapeutic Plasma Exchange System  
Extracorporeal Shock Wave Renal Lithotripter

RADIOLOGY DEVICE PANEL

Hyperthermia System for Palliative Management of Malignant Tumors

MICROBIOLOGY DEVICES PANEL

- \*Automated Antimicrobial Susceptibility Test System
- \*Hepatitis Test System
- \*Gonococcal Antibody Test (GAT) (866.3290)

IMMUNOLOGY DEVICES PANEL

- \*Alpha-Fetoprotein (AFP) Test System as an aid in the diagnosis of  
neural tube defect (NTD)
- Alpha-Fetoprotein (AFP) Test System as an aid in the detection and  
management of cancer
- \*Carcinoembryonic Antigen (CEA) Immunological Test System as an aid in  
the detection and management of cancer (866.6010)

CLINICAL CHEMISTRY DEVICES PANEL

Estrogen Receptor Assay System  
Cyclosporin Assay System

CIRCULATORY SYSTEM DEVICES PANEL

- \*Replacement Heart Valve (870.3925)
- \*Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon  
Dilatation Catheter
- \*Implantable Pacemaker Pulse Generator (870.3610)
- \*Pacemaker Programmer (870.3700)

OPHTHALMIC DEVICES PANEL

- \*Soft (hydrophilic) Contact Lens (886.5925)
- \*Rigid Gas Permeable Contact Lens (886.5916)
- \*Soft (hydrophilic) Contact Lens Solution (886.5928)
- \*Rigid Gas Permeable Contact Lens Solution (886.5918)
- \*Contact Lens Heat Disinfection Unit (886.5933)
- \*Intraocular Lens (886.3600)
- \*Intraocular Fluid (886.4275)
- \*NE: YAG Ophthalmic Laser for Iridectomy (Iridotomy) and Pupillary Membranectomy

\*4-Of-A-Kind Approved Before 1988