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PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国医药行业标准

YY/T 0660–2008

Standard specification for polyetheretherketone (PEEK) polymers for surgical implant applications

外科植入物用聚醚醚酮（PEEK）聚合物的标准规范

(ASTM F2026-07, MOD)

Issued on April 25, 2008 **Implemented on June 01, 2009**

Issued by SFDA (State Food and Drug Administration)

Contents

Foreword

This Standard is revision of ASTM F2026-07 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications, technical contents is consistence.

Comparison with ASTM F2026-07, main differences of this standard are as follows:

— Revision of writing format according to Chinese habit;

— Changed the description of USA standards as National standard;

— Changed the International standard in Normative references of clause 2 as National standards

— Modified the writing incorrect contents in Table 1;

— Deleted the KEY in clause 8.

Annex A of this standard is informative annex.

This Standard is proposed and under the jurisdiction of National Technical Committee on Biological Evaluation on Medical Device of Standardization Administration of China.

The drafting organizations are Tianjin Medical Device Quality Supervision and Inspection Center of State Food and Drug Administration.

The chief drafting staff of this Part includes Ma Chunbao, Fan Bo, Li Ruan and Jiang Xi.

Standard specification for polyetheretherketone (PEEK) polymers for surgical implant applications

1 Scope

This standard covers polyetheretherketone (PEEK) polymer in virgin forms as supplied by a vendor (pellets, powder, and so forth). It provides requirements and associated test methods for these thermoplastics when they are to be used in the manufacture of intracorporeal devices such as surgical implants or components of surgical or dental devices.

As with any material, some characteristics may be altered by the processing techniques (molding, extrusion, machining, assembly, sterilization, and so forth) required for the production of a specific part or device. Therefore, proper-ties of fabricated forms of these polymers should be evaluated using test methods which are appropriate to ensure safety and efficacy as agreed upon by the vendor, purchaser, and regulating bodies.

The properties included in this specification are those applicable for PEEK polymers only. Indicated properties are for injection molded forms. Fabricated forms, material or forms containing colorants, fillers, processing aids, or other additives, as well as polymer blends which contain PEEK, or reclaimed materials, are not covered by this specification.

This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable level of confidence concerning the performance of virgin PEEK polymers for use in medical implant devices. The properties listed should be considered in selecting material(s) in accordance with the specific end-use requirements.

When evaluating material in accordance with this specification, hazardous materials, operations, and equipment may be involved. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

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