of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that, for manufacturers not planning to submit a PMA immediately, an IDE application should be submitted to FDA at least 30 days before the end of the 90 day period after the final rule is published in the Federal Register to minimize the possibility of interrupting all availability of the device. FDA does not consider an investigation of the partially fabricated denture kit to pose a significant risk as defined in the IDE regulation. The device may be distributed for investigational use if manufacturers, importers, or other sponsors comply with the abbreviated requirements (§812.1(b)) of the IDE regulation.

C. Description of Device

A partially fabricated denture kit is a device composed of connected preformed teeth that is intended for use in construction of a denture. A denture base is constructed using the patient's mouth as a mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are chemically bonded to the base.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring partially fabricated denture kits to have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the device.

E. Risk Factors

Partially fabricated denture kits have been associated with potential risks relative to jaw relationships, adverse tissue reaction, and materials composition.

The risks associated with jaw relationships are: (1) Inaccurate vertical dimension of occlusion; (2) improper occlusal plane and tooth ridge relationships; (3) jaw joint dysfunction and esthetic problems caused by inaccurate reproduction of the physiologic dimensions of the mandible; and (4) unsatisfactory centric and eccentric relations to ensure proper distribution of pressure to the edentulous-bearing areas. The risks related to adverse tissue reaction include: (1) Irritation of the oral cavity soft tissues; (2) monilial infection; (3) unusual hard and soft tissue changes; (4) tissue health maintenance difficulties; and (5) allergy or sensitization caused by the leaching of unreacted resin monomer on initial fitting or insertion of the denture.

The risks relative to materials composition: (1) Deterioration of the acrylic plastic denture base over time; (2) unsatisfactory performance of the denture materials; and (3) ill-fitting dentures resulting from decomposition or distortion of the acrylic plastic caused by improper finishing techniques and jeopardy to the patient's oral health resulting from the use of dentures fabricated by dental office techniques that bypass traditionally controlled, accepted, and proven laboratory procedures (Refs. 1 through 10).

F. Benefits of the Device

A partially fabricated denture kit is constructed by chemically bonding preformed teeth to a common base. The patient's mouth is used as a mold by partially polymerizing the resin denture base while the materials are in contact with oral tissues. The potential benefits intended from the use of a partially fabricated denture kit are: potential modification of the size and shape of the prefabricated denture to the specific oral configuration and relationships for some patients; a reduction in the amount of time needed by the practitioner and auxiliary staff to fabricate a denture for the patient; fewer laboratory procedures compared with conventional methods of denture construction outside the dental office; reduction of commercial laboratory charges and potential reduction of denture costs to the patient; and availability of a denture intended for temporary use. (Refs. 1, 3 through 5, 8, and 10).

G. Need for Information for Risk/Benefit Assessment of the Device

FDA classified the partially fabricated denture kit into class III because it determined that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has determined that the special controls that may now be applied to class II devices under the Safe Medical Devices Act of 1990 also would not provide such assurance. FDA has weighed the probable risks and benefits to the public health from the use of the device and believes that the

literature reports and other information discussed above suggest the potential for unreasonable risks associated with the use of the device. These risks must be addressed by the manufacturers of partially fabricated denture kits. FDA believes that partially fabricated denture kits should undergo premarket approval to establish effectiveness and to determine whether the benefits to the patient are sufficient to outweigh any risk.

II. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the act and §814.20 (21 CFR 814.20) of the procedural regulations for PMA's. Such a PMA should include a detailed discussion of the risks identified above, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known to the applicant that have not been identified in this document; (2) the effectiveness of the specific partially fabricated denture kit that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence as defined in § 860.7 and should be obtained from wellcontrolled clinical studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the partially fabricated denture kit for its intended use. In addition to the basic requirements described in § 814.20(b)(6)(ii) for a PMA, it is recommended that such studies employ a protocol that meets the criteria described below.

Applicants should submit any PMA in accordance with FDA's guideline entitled "Guideline for the Arrangement and Content of a PMA Application." The guideline is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850.

A. General Protocol Requirements

The partially fabricated denture kit should be evaluated in a prospective, randomized, controlled clinical trial that uses adequate controls. The study must attempt to answer all of the general and specific questions about the safety and effectiveness of the devices, including the risk to benefit ratio. These questions should relate to the pathophysiologic effects which the