Convenience Kits
Interim Regulatory Guidance

This document is intended to provide guidance regarding a new premarket notification regulatory strategy for convenience kits. It does not create or confer any 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. Public input on this document was not obtained prior to implementation because it is believed that this guidance presents a less burdensome policy that is consistent with public health.

Premarket Notification (510(k)) Staff
Program Operations Staff
Office of Device Evaluation

May 20, 1997

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by contacting the Premarket Notification (510(k)) Section at 301-796-5640. For questions regarding the use or interpretation of this guidance, contact the Premarket Notification (510(k)) Section at 301-796-5640.

U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

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As part of the Center for Devices and Radiological Health's organizational transformation initiative, the 510(k) Process Reengineering Team has been carefully examining the Premarket Notification (510(k)) Program to insure that it is operating at peak efficiency and that the optimum public health benefit is achieved given the allotted resources.

During the preliminary examination of the requirements and execution of the 510(k) Program, the Team identified a change to the Program that may reduce the regulatory burden for assemblers of convenience kits. Outlined below is a new regulatory approach to be applied to convenience kits which could result in a decrease in the number of 510(k) submissions for these devices and, in so doing, will save ODE review resources. It is estimated that the Office of Device Evaluation (ODE) receives approximately 300 510(k) submissions per year that could be impacted by this regulatory approach.

Background

Under the current regulations, first time marketers of devices must submit a premarket notification and obtain clearance for a device before it can be lawfully introduced into interstate commerce. Assemblers/manufacturers of convenience kits who intend to market these devices for the first time are subject to these requirements.

Many of the kits that have been the subject of 510(k) review are comprised of legally marketed devices that are simply being assembled in kit form strictly for the "convenience" of the purchaser or user, thus the term "convenience kit." During the review of convenience kit 510(k)s, ODE has traditionally focused its efforts on the intended use(s) of the particular type of kit, the device components that are included in the kit, and the impact that any further processing may have on the kit and/or its components. The labeling for these kits tends to be rather basic, identifying the assembler or manufacturer of the particular kit and the intended use(s). Additional processing typically involves affixing the label to the outside packaging of the kit and terminal sterilization of the kit and its components.

New Regulatory Approach

Based on this experience, FDA believes that under certain circumstances premarket clearance for convenience kits may not be necessary to ensure protection of the public health. Accordingly, FDA intends to propose rulemaking to exempt certain, specifically identified convenience kits from the requirement of premarket notification. Until such a rule is in effect, FDA intends to exercise enforcement discretion regarding the requirement for premarket clearance for

convenience kits that conform with the specific limitations regarding intended use, components, and processing described below.

1. Intended Use - Using the 510(k) database, ODE has developed the attached list of generic types of kits that the Agency believes represents established intended use(s) for convenience kits and that does not modify the intended use(s) of the individual kit components. FDA recognizes that additional types of kits may currently exist that should be subject to this guidance. Likewise, FDA anticipates that other types of kits may become eligible for consideration in time. Thus, the list may be periodically updated based on the Agency's experience with this new regulatory approach as well as on comments received from interested parties.

2. Components - Convenience kits subject to this guidance should only include components that are either: (1) legally marketed preamendments devices, (2) exempt from premarket notification, or (3) have been found to be substantially equivalent through the premarket notification process. The components should be purchased in finished form, i.e., they should be packaged, labeled, etc., consistent with their legal marketing authorization.

3. Processing - This guidance only applies in instances where the kit assembler/manufacturer concludes that further processing, if any, of the kit does not significantly affect the safety or effectiveness of any of the kit's components. In making this determination, FDA recommends that kit manufacturers follow the procedures described in FDA's guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." It is the responsibility of each kit assembler/manufacturer to carefully consider the impact that any processing may have on the kit's components.

In the past, sterilization has been a focus of the 510(k) review for convenience kits; therefore, kit assemblers should carefully consider the impact of the sterilization process on individual kit components. If the kit's components may be sensitive to further processing, e.g., surgical sutures, the assemblers/manufacturers should take measures necessary to ensure that the components are not adversely affected by the reprocessing procedures.

In summary, FDA intends to exercise its enforcement discretion, i.e. not require 510(k) clearance, for convenience kits of a type matching one of those included on the attached list, consisting of components that have been cleared through the 510(k) process, and where the assembler/manufacturer is able to reasonably conclude that any further processing of the kit and its components does not significantly affect the safety or effectiveness of any of its components. Documentation to support each of these determinations should be maintained in the assembler's/manufacturer's files in accordance with the Quality System regulation (21 CFR 820) and should be available for FDA review if needed. It should be noted that while FDA intends to exercise enforcement discretion with respect to premarket notification requirements, assemblers/manufacturers of convenience kits are still required to comply with other general controls including registration, listing, prohibition against misbranding, and good manufacturing practices. In the future, FDA intends to propose rulemaking to formally exempt these types of kits from the requirement of premarket notification.

Limitations

FDA does not intend to propose regulatory changes relating to drug requirements for convenience kits. For convenience kits that contain components subject to regulation as drugs, the assembler/manufacturer should contact the Center for Drug Evaluation and Research, Division of Prescription Drug Compliance & Surveillance, at (301) 594-0101 regarding premarket requirements for the drug components in the kit.

This guidance is not intended to apply to kit 510(k)s that are under the jurisdiction of the Center for Biologics Evaluation and Research. For information regarding kits reviewed by CBER, the assembler/manufacturer should contact the Office of Blood Research and Review, Division of Blood Applications, Biologics Devices Branch at (301) 827-3524.

Effective Date

This guidance is effective immediately.

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Types of Convenience Kits

The attached list of convenience kits was developed based on FDA's database and is organized by medical speciality. For purposes of this document, the terms "kit," "set," and "tray" are considered synonymous. This list may be periodically updated based on the Agency's experience with this guidance as well as on comments received from interested parties.

Name of Kit/Tray/Set and Intended Use (if Needed)

Anesthesiology Devices

Airway Suction Kit
Anesthesia Breathing Circuit Kit (Adult & Pediatric)
Anesthesia Conduction Kit
Anesthesia Kit
Arterial Blood Sampling Kit
Blood Specimen Collection Kit (Excludes HIV Testing)
Brachial Plexus Anesthesia Kit
Caudal Anesthesia Kit
Continuous Brachial Plexus Block Tray
Custom Anesthesia Tray
Epidural Anesthesia Kit
Glossopharyngeal Anesthesia Kit
Humidifier - Nebulizer Kit
Laryngoscope Kit
Nasal Endotracheal Tube Holder Kit
Nerve Block Tray
Orotrachael Intubation Guide Kit
Oxygen Administration Kit
Regional Anesthesia Kit
Spinal Anesthesia Kit
Spinal Epidural Anesthesia Kit
Tracheal Suction Set
Tracheobronchial Suction Catheter Kit
Tracheostomy and Nasal Suctioning Kit
Tracheotomy Care Kit

Cardiovascular Devices

Angiography/Angioplasty Kit
Angioscopic Valvulotome Kit
Cardiac Catheterization Kit
Cardioplegia Solution Administration Kit
Cardiopulmonary Bypass Catheter Kit
Cardiopulmonary Resuscitation Aid Kit
Cardiovascular Catheter Sheath Introducer Kit
Cardiovascular Procedure Kit
Cardiovascular Surgical Instruments Tray
Catheter Balloon Repair Kit
Catheter Guide Wire Kit
Catheter Introducer Kit
Central Venous Blood Pressure Kit
Central Venous Catheter Tray
CT Biopsy Tray
Digital Angiography Tray
Endothelial Cell Harvesting Kit
Laser Blood Flow Kit
Lead Introducer Kit
Percutaneous Atrial Catheter Kit
Percutaneous Sheath Introducer Kit
Phlebotomy Blood Collection Kit
Winged Intravenous Catheterization Kit

Clinical Chemistry and Clinical Toxicology Devices

Blood Alcohol Kit (Excludes HIV testing)
Blood and Urine Collection Kit (Excludes HIV testing)
Neonatal Blood Collection Kit and Screening Form (Excludes HIV testing)
Sex Crimes/Sexual Assault/Suspect Evidence Collection Kit (Excludes HIV testing)
Urine Collection Kit (Excludes HIV testing)
Urine Transport Kit (Excludes HIV testing)

Dental Devices

Dental Hygiene Kit
Dental Implant Surgical Tray
Dental Prophylaxis Kit
Denture Repair Kit
Endodontic Kit
Fixture Mount Kit
General Purpose Dental Tray
Gingival Retraction Kit
Lapping Tool Kit
Oral Surgery Tray
Plaque Disclosing Kit
Prophylaxis Kit
Restorative Instrument and Component Tray

Ear, Nose, and Throat Devices

Cricothyrotomy Kit
Ear Irrigation Kit
Ear, Nose, and Throat Surgical Tray
Myringotomy Procedure Kit
Oral Irrigation Kit
Pierced Ear/Entry Cleaning Tray
Tracheostomy Cleaning Tray
Tracheostomy Kit

Gastroenterology-Urology Devices

Anti-Regurgitation Blood Tubing Kit
Balloon Gastrotomy Tube Kit
Barium Enema Kit
Biopsy Needle Kit
Bladder Irrigation Kit
Body Fluids Barrier Kit
Bulb Irrigation Tray
Catheter Care Tray
Catheter (Insertion) Tray
Cholangiogram Catheter Kit
Continuous Arteriovenous Hemofiltration Catheter Kit
Declotting Tray

Dialysis Administration Kit
Dialysis On/Off Kit
Dialyzer Holder Set
Dual Lumen Catheter Tray
Electrosurgical Electrode Kit
Endoscope Introducer Kit
Endoscopic Cholangiogram Kit
Enema Kit
Enteral Administration Kit (Adult & Pediatric)
Esophageal Dilator Kit
Feeding Tube Kit
Femoral Catheter Kit
Flexible and Rigid Choledochoscope Kit
Foley Catheter Kit (Excludes HIV Testing)
Gastric Colonic Catheter Irrigation Kit
Gastric Irrigation and Aspiration Kit
Gastric Lavage Kit (Adult or Pediatric Use)
Gastro-Urology Biopsy Kit
Gastrointestinal Tube Kit
Gastrostomy Guide Wire Placement Kit
Gastrostomy Jejunostomy Feeding Tube Kit
Gastrostomy Tube Kit
Hemodialysis Tray
Kidney Perfusion Kit
Laparoscopic Cholangiogram Catheter Kit
Laparoscopic Gastrostomy Kit
Laparoscopic Jejunostomy Kit
Laparoscopy Kit
Male External Catheterization Kit (Excludes HIV Testing)
Multi-Lumen Hemodialysis Catheterization Kit
Nasogastric Feed Tube Kit
Nasogastric-Gastrojejunal Kit
Needle Catheter Jejunostomy Kit
Nephroscope Set
Non-Balloon Replacement Gastrostomy System
Ostomy Care Kit
Percutaneous Endoscopic Gastrostomy Kit
Percutaneous Replacement Gastrostomy Tube Kit
Percutaneous Cholangiogram Kit
Perineal Irrigation Kit
Peritoneal Dialysis Administration Kit
Peritoneal Dialysis Tubing Kit
Personal Erection Kit

Rectal Dilator Kit
Replacement Gastrostomy Feeding Catheter Tray
Single Needle with Uni-Directional Pump Kit
Single Needle (Co-Axial Flow) Dialysis Kit
Sterile Infant Gavage Kit
Subclavian Catheter Kit
Suprapubic Cystostomy Catheter Kit
Universal Drainage Tray
Urinary Irrigation Kit
Urinary Drainage Collection Kit
Urinary Catheterization Kit (Excludes HIV Testing)

General and Plastic Surgery Devices

Aspiration Tray
Basic Set-Up Tray
Bone Marrow Biopsy Tray
Bowel Kit
Breast Biopsy/Localization Tray
Burn Dressing Tray
Burn Kit
Cement and Bone Removal Kit
Cholecystectomy Kit
Debridement Tray
Decontamination Kit
Dressing Change Tray
First Aid Kit
Fluid Drainage Tray
General Purpose Instrument Tray
General Surgery Tray
Herniorrhaphy Kit
Hysterectomy Kit
Incision and Drainage Tray
Irrigation Kit (Wounds)
Laceration Tray
Laparoscopic Cholecystectomy Kit
Laparoscopic Sphincterotomy Kit
Liver Biopsy Kit
Minor Surgical Procedures Tray
Operating Room Accessories Table Tray
Paracentesis Tray
Pelviscopy Kit

Plastic Surgery and Accessories Kit
Shave Prep Kit
Single Use Instrument Tray
Skin Prep Tray
Staple Removal Kit
Sterile Puncture Tray
Sterilization Wrap Tray
Suction Catheter Kit
Surgical Instrument Tray
Surgical Retractor Kit
Suture Kit
Suture Removal Kit
Thoracic Catheter Insertion Tray
Tourniquet Kit
Ulcer Wound Tray
Vacuum Powered Body Fluid Collection Kit
Venous Ulcer Kit
Wound Drainage Kit
Wound Dressing Kit

General Hospital and Personal Use Devices

Admission Kit (Patient Utensil)
Anaphylactic Emergency Kit
Baby Care Kit
Blood Administration Kit
Blood Borne Pathogen Response Kit
Blood Sampling Kit (Excludes HIV Testing)
Blood Transfusion Kit
Body Fluid Barrier Kit
Body Fluid Clean Up Kit
Body Fluid Disposal Kit
Bone Marrow Collection/Transfusion Kit
Buret Administration Intravenous Kit
Catheter Repair Kit
Central Venous Catheter Dressing Change Kit
Chemotherapy Administration Kit
Chemotherapy Spill Clean-up Kit
Chest Drainage Kit
Clean-Up Kit
Delivery Room Apparel Kit
Emergency Response Safety Kit

Fever Monitoring Kit
I.V. Start Kit
Insect Sting Emergency Kit
Intra-Arterial Administration Kit
Intravenous Extension Tubing Kit
Lumbar Puncture Tray (Adult & Pediatric)
Medical Procedure Tray
Microsurgical Instrument Tray
Mid-Stream Collection Kit
Mortician's Kit
O.R. Scrub Prep Tray
Oral Administration Set
Parenteral Administration Kit
Parenteral Supply Kit
Percutaneous Introducer Kit
Peripheral Catheter Insertion Kit
Personal Protection Kit
Port Introducer Kit
Prep Kit
Pressure Monitoring (Air/Gas) Kit
Sitz Bath Kit
Snake Bite Kit
Snake Bite Suction Kit
Spill Kit
Survival Kit
Thermometer Kit
Thoracentesis Tray
Ultrasonic Aspiration Biopsy Kit
Umbilical Catheter Insertion Tray
Vascular Access Port Kit
Venipuncture Kit
Vomitus Clean-Up Kit

Neurological Devices

Endoscopic Shunt Placement Kit
Endoscopic Ventricular Catheter Placement Kit
Intracranial Pressure & Temperature Monitoring Kit
Lumbar Drainage Catheter Kit
Lymphangiographic Kit
Myelogram Kit
Neurological Test Kit
Neurological Tray

Obstetrical and Gynecological Devices

Amniocentesis Tray
Breast Pump Kit
Cervical Smear Kit
Cesarean Section Tray
Circumcision Tray
Culdocentesis Kit
Cytology Kit
D&C Tray
Delivery Kit
Emergency Obstetrical Kit
Endometrial Sampling Kit
Fetal Blood Sampling Kit (Excludes HIV Testing)
Forensic Evidence Sexual Assault Kit
Gynecological Laparoscopic Kit
Labor and Delivery Kit
Maternity Kit
Obstetrical Kit
Obstetrical Anesthesia Kit
Obstetrical Vacuum Delivery Kit
Pap Smear Kit
Paracervical Anesthesia Kit
Pelvic Exam Kit
Pudendal Anesthesia Kit
Seminal Fluid Collection Kit
Trocar Kit
Vaginal Examination Tray
Vasovasostomy Set

Opthalmic Devices

Eye Tray
IOL Tray
Phaco Kit
Surgical Eye Tray
Vitrectomy Kit

Orthopedic Devices

Disposable Joint Aspiration/Injection Kit
Endoscopic Plantar Kit
Graft Harvesting Kit
Laparoscopic Bone Anchor Urethropexy Instrument Kit
Orthopedic Tray
Pre-Drill Kit for Cartilage Re-surfacing
Surgical Cannulaes & Depth Gauge Kit for Arthroscopic Procedures
Surgical Kit
Transtibial Anterior Cruciate Ligament Kit

Physical Medicine Devices

Hand Accessory Kit

Radiology Devices

Arthrogram Tray
Biopsy Needle Guide Kit
Dental Tray
Discography Kit
MRI Disposable Kit
Prostate Seeding Kit
Radiographic Contrast Tray
Radiology-Diagnostic Kit

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