PREMARKET CONSIDERATIONS IN THE POSTMARKET ENVIRONMENT

FDA/XAVIER UNIVERSITY MEDCON CONFERENCE

MAY 3, 2017

STEVEN NIEDELMAN
LEAD QUALITY SYSTEM & COMPLIANCE CONSULTANT
KING & SPALDING LLP
SNIEDELMAN@KSLAW.COM
202-626-2942

PHILLIP PONTIKOS
NATIONAL MEDICAL DEVICE EXPERT
U.S. FOOD AND DRUG ADMINISTRATION
PHILLIP.PONTIKOS@FDA.HHS.GOV
614-227-5780

PREMARKET CONSIDERATIONS

- Premarket considerations and decisions should not be limited to obtaining obtain initial marketing clearance for your device – but should be made throughout the lifecycle of your marketed device, and should be considered whenever there is a change made to your existing device
- Many postmarket events should prompt premarket clearance considerations and decisions points which should be contained in procedures to ensure appropriate and consistent decisions
- Establishments should follow FDA regulations, guidances, internal procedures, and product related decision trees so as to consistently evaluate the need for obtaining new 510(k) clearance when appropriate
- Failure to obtain a new 510(k) when deemed necessary for changes made post-clearance misbrands your device, as the modified device has not been found substantially equivalent to a predicate device, as well as adulterates your device since the device has not been found SE to a predicate device, thereby requiring an approved application for premarket approval (PMA).

POSTMARKET EVENTS THAT WOULD REQUIRE PREMARKET CONSIDERATIONS AND DECISIONS

- Design changes
- Recall – Correction and/or Removal
- Technical Bulletins
- Critical supplier issues/changes
- Enhanced product lines: adding additional models and/or expanded claims for existing models
- Design creep, that when evaluated in the totality of minor changes, has resulted in significant device design changes
- Changes to cleaning processes
- Becoming aware of changes in intended use by how your device is being used in the market (21CFR 801.4)
- Changes in indications for use
- Changes in sterilization modality that may require clearance
- Others….

DESIGN CONSIDERATIONS

Marketed Devices:

- Redesign of your device
- Packaging changes
- Critical component changes
- Sizes within a product family
- Introduction of new models of the existing device
- Software changes and software validation

Investigational Devices:

- Collect data to evaluate the future need for obtaining premarket clearance
- No obligation to obtain clearance during investigational phase
  - Investigational design is not to commercially marketed with cleared devices
- Upon completion of study – evaluate need for premarket clearance and do not continue marketing until clearance is granted

MANAGING PREMARKET ISSUES DURING AN INSPECTION

- The Investigators Operations Manual (IOM) states 510(k) issues shall not be typically identified on FDA-483 List of Observations
  - Investigators may express their concern regarding the need for a 510(k), but final decision rests with CDRH/ODE
- Information and documentation regarding potential 510(k) issues are typically collected during an inspection for review by appropriate Division within the Office of Device Evaluation (CDRH)
  - Information collected includes labeling along with changes to the design, software, cleaning procedures, etc.
- Depending upon the length of the inspection and responsiveness from ODE, their review may be completed and opinion rendered prior to the completion of the inspection. In those situations, 510(k) related findings may be included as a FDA-483 Observation
- The concerns and need for 510(k)s will be included in the Discussion with Management at the conclusion of the inspection, which along with all other observations and recommendations, should be well understood by management, taken seriously and begin appropriate follow-up with CDRH/ODE
- At times, Investigators may be accompanied by CDRH personnel from ODE, Office of Science and Engineering Laboratories (OSEL). During these inspections accompanying expertise may be able to support 510(k) findings at the outcome of the inspection.