List of Highest Priority Devices for Human Factors Review

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Document issued on February 3, 2016.

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For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

Preface

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I. Introduction

FDA is issuing this guidance document in order to inform medical device manufacturers which device types should have human factors data included in premarket submissions (i.e., for PMA, 510(k)). FDA believes these device types have clear potential for serious harm resulting from use error, and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

FDA issued the guidance document, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff*, to assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses and use environments.

For devices that should include human factors data in premarket submissions, as listed here, manufacturers should provide FDA with a report (see Appendix A of *Applying Human Factors and Usability Engineering to Medical Devices*) that summarizes the human factors or usability engineering processes they have followed, including any preliminary analyses and evaluations and human factors validation testing, results and conclusions.

III. List of Device Types for Which Human Factors Data Should be Submitted for Review

CDRH considers human factors testing a valuable component of product development for medical devices. CDRH recommends that manufacturers consider human factors testing for medical devices as a part of a robust design control subsystem. However, in an effort to make CDRH's premarket submission expectations clear, CDRH has identified circumstances under which human factors validation testing should be submitted in a premarket submission. These devices noted below were selected because they have clear potential for serious harm resulting from use error. This identification was based on knowledge gleaned through Medical Device Reporting (MDRs) and recall information. Human factors data should be included in premarket submissions for these devices unless the submission does not involve any changes to users, user tasks, user interface, or use environments from those of the predicates.

- Ablation generators (associated with ablation systems, e.g., LPB, OAD, OAE, OCM, OCL)
- Anesthesia machines (e.g., BSZ)
- Artificial pancreas systems (e.g., OZO, OZP, OZQ)
- Auto injectors (when CDRH is lead Center; e.g., KZE, KZH, NSC)
- Automated external defibrillators (e.g., MKJ, NSA)
- Duodenoscopes (on the reprocessing; e.g., FDT) with elevator channels
- Gastroenterology-urology endoscopic ultrasound systems (on the reprocessing; e.g., ODG) with elevator channels
- Hemodialysis and peritoneal dialysis systems (e.g., FKP, FKT, FKX, KDI, KPF ODX, ONW)
- Implanted infusion pumps (e.g., LKK, MDY)
- Infusion pumps (e.g., FRN, LZH, MEA, MRZ)
- Insulin delivery systems (e.g., LZG, OPP)
- Negative-pressure wound therapy (e.g., OKO, OMP) intended for use in the home
- Robotic catheter manipulation systems (e.g., DXX)
- Robotic surgery devices (e.g., NAY)
- Ventilators (e.g., CBK, NOU, ONZ)
- Ventricular assist devices (e.g., DSQ, PCK)

Note that FDA may recommend or require that human factors data be included in premarket submissions for additional device types though product specific guidance documents, special

controls guidance or guideline documents, or special controls contained in medical device classification regulations. Premarket reviewers may also determine that human factors data are needed in specific premarket submissions on a case-by-case basis (see Section IV below).

IV. How this List Should be Used for Premarket Submissions

For device types on the list: Any premarket submission for the device types listed above should include either a human factors test report and data as described in *Applying Human Factors and Usability Engineering to Medical Devices* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259760.pdf), or should provide a detailed rationale that supports the conclusion that human factors data are not necessary. In essence, this rationale would be based on analysis of risk associated with users, uses, and use environments and results of that analysis would indicate that the severity of the potential harm resulting from use error is not serious.

For device types not on the list: Submissions for device types not on the list above should contain human factors data if analysis of risk indicates that users performing tasks incorrectly or failing to perform tasks could result in serious harm. ODE may also determine that human factors data are needed in a specific premarket submission on a case-by-case basis when one or more of the following apply:

- **Submission type:** Premarket Application (PMA) or De Novo Petition for a device that has potential for serious harm resulting from use error
- **User interface modification:** New or different user interface features were implemented to satisfy a special control[1] or recommendation (in a device-specific guidance document) related to its use
- **Different users:** The submission includes a change of intended users, for instance the new device is intended for use by lay users when the predicates were labeled for use only by healthcare professionals and device use has potential for serious harm resulting from use error
- **Recalls, adverse events, and problem reports:** The device type has been associated with recalls, adverse events, problem reports or complaints for which the cause has been attributed to use error or use error is the only explanation
- **Device modifications:** The device was modified or differs from the predicate in any of the following ways and the device has potential for serious harm resulting from use error:
  - The user interface has been modified (even if it has been simplified)
  - User tasks have been added or changed
  - The severity of possible harm resulting from use error has increased

[1] Special controls are regulatory requirements for class II devices and are usually device specific. These controls can include premarket data requirements.

158 ○ The device will be used in a new use environment (e.g., in the home or a moving
159 vehicle)