December 31, 2019

Sean Honard
Sr. Regulatory Affairs Specialist
Stryker Medical
3800 East Centre Avenue
Portage, MI 49002

Re: Class II 510(k) Exemption Petition for Powered Wheeled Stretchers
Docket Number: FDA-2019-P-3347
Petition Received: July 10, 2019

Dear Mr. Honard:

The Food and Drug Administration (FDA) has reviewed the above referenced petition for exemption from premarket notification (510(k)) pursuant to section 510(m)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This petition seeks exemption from 510(k) requirements for powered wheeled stretchers, which are battery-powered tables with wheels that are intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions). Powered wheeled stretchers are currently regulated as class II devices under 21 CFR 890.3690, product code INK, and require premarket notification under section 510(k) of the FD&C Act.

On September 16, 2019, FDA published a notice of your petition in the Federal Register and provided an opportunity for interested persons to submit comments on it, in accordance with section 510(m)(2) of the FD&C Act (see 84 FR 48623). FDA received no comments. After reviewing the petition, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of powered wheeled stretchers, as long as the conditions for 510(k) exemption listed below are met. Therefore, FDA is granting your petition.

FDA will publish an order in the Federal Register exempting powered wheeled stretchers from 510(k) requirements, as long as they meet the conditions described below, subject to the limitations on exemption in 21 CFR 890.9. This device is identified as a "powered wheeled stretcher," and defined as "a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions)." This device will continue to be a class II device under 21 CFR 890.3690, "Powered wheeled stretchers" and will remain under product code INK.

The following conditions must be met in order for the device to be 510(k)-exempt:

(1) Appropriate analysis and non-clinical testing must demonstrate that the safety controls are adequate to ensure safe use of the device and prevent user falls from the device in the event of a device failure;

(2) Appropriate analysis and non-clinical testing must demonstrate the ability of the device to withstand the rated user weight load with an appropriate factor of safety;

(3) Appropriate analysis and non-clinical testing must demonstrate the longevity of the device to withstand external forces applied to the device and provide the user with an expected service life of the device;

(4) Appropriate analysis and non-clinical testing must demonstrate proper environments of use and storage of the device to maximize the longevity of the device;

(5) Appropriate analysis and non-clinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate electromagnetic compatibility and electrical safety;

(6) Appropriate analysis and non-clinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the skin-contacting components of the device are biocompatible;

(7) Appropriate analysis and non-clinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate the software life cycle and that all processes, activities, and tasks are implemented and documented;

(8) Appropriate analysis and non-clinical testing must validate that the device components are found to be non-flammable;

(9) Appropriate analysis and non-clinical testing (such as outlined in appropriate FDA-recognized consensus standards) must validate that the battery in the device performs as intended over the anticipated service life of the device;

(10) Adequate labeling is provided to the user to document proper use and maintenance of the device to ensure safe use of the device in the intended use environment; and

(11) Appropriate risk assessment, including, but not limited to, evaluating the dimensional limits of the gaps in hospital beds, and mitigation strategy to reduce entrapment.

A number of these conditions for exemption involve "appropriate analysis and nonclinical testing" the details of which can be found in, among other places, certain FDA-recognized consensus standards. Below is a list of FDA recognized consensus standards[1] that may be used to meet the listed conditions of exemption:

- ANSI/AAMI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI/IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,
- ISO 7176-14: Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
- ISO 7176-21: Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
- ANSI/AAMI/ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI/AAMI/ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- AAMI/ANSI/ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- IEC 62304: Medical device software - Software life cycle processes
- ISO 7176-25: Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs.

We also recommend you consider FDA's guidance "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment," when considering the appropriate analysis and risk assessment referenced in the conditions set forth above.

If you have any questions related to this letter, please contact Dr. Eric Franca, by telephone at (301) 796-4505, or by email at eric.franca@fda.hhs.gov.

Sincerely,

Ellen J. Flannery, JD
Deputy Center Director for Policy
Center for Devices and Radiological Health

[1] For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm