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Citizen Petition

The undersigned submits this petition under 510(m)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) to request the Commissioner of Food and Drugs to exempt 21 CFR §890.3690 from premarket notification as required under 510(k) of the Act.

A. Action Requested

The undersigned is requesting an amendment to regulation 21 CFR §890.3690, Powered Wheeled Stretcher, to exempt the classification from premarket notification.

21 CFR §890.3690, Powered Wheeled Stretcher, currently states:

> (a) Identification. A powered wheeled stretcher is 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).
>
> (b) Classification. Class II (performance standards).

The undersigned requests the following amendment to 21 CFR §890.3690, as noted in the underlined section:

> (a) Identification. A powered wheeled stretcher is 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).
>
> (b) Classification. Class II (performance standards). <u>The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 890.9.</u>

B. Statement of Grounds

The statutory authority for this petition seeking exemption of devices classified under 21 CFR §890.3690 from premarket notification is found in Section 510(m)(2) of the Federal Food, Drug, and Cosmetic Act, which currently states:

> *"…the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device."*

Devices classified under the subject regulation (21 CFR §890.3690, Powered Wheeled Stretcher) share many critical and distinguishing features with devices that the FDA has already deemed exempt from premarket notification. These features lend to similar safety and effectiveness profiles. These comparable device classifications will be referenced throughout

the petition to provide precedential support for the fact that a premarket notification is not necessary to assure the safety and effectiveness of devices currently regulated by 21 CFR §890.3690.

- 21 CFR §890.3110, Electric Positioning Chair
- 21 CFR §880.6775, Powered Patient Transfer Device
- 21 CFR §880.5500, AC-powered Patient Lift
- 21 CFR §880.5100, AC-powered Adjustable Hospital Bed

Below is a discussion of the similarities between the Powered Wheeled Stretcher classification regulation and the exempted devices referenced above. The factual grounds upon which this petition relies, in accordance with the guidance document "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff" (1998) are as follows.

1. **These devices do not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the devices.**

   A review of the Manufacturer and User Facility Device Experience (MAUDE) database for 21 CFR §890.3690, product code INK, from May 30, 2014 to May 30, 2019 generated 120 Medical Device Reports. The adverse events were comprised of 9 injuries and 111 malfunctions. No reports of deaths were documented.

   The malfunctions were primarily related to unintended engagement/disengagement of the powered drive feature or difficulty to engage/disengage the braking system. No patient-related injuries were reported. The caregiver-reported injuries were as follows:

   - 4 reported injuries were alleged to involve the braking system.
   - 2 reported injuries were alleged to involve the unintended disengagement of the powered drive feature.
   - 1 reported injury was alleged to involve the unintended acceleration of the powered drive feature.
   - 1 reported injury was alleged to involve a broken IV pole attached to the stretcher.
   - 1 reported injury was alleged to involve an attempt to move the stretcher sideways.

   A complete list of the nine injury reports from the MAUDE database is provided in Appendix A.

   A survey of Medical Device Reports from May 30, 2014 to May 30, 2019 for 21 CFR §890.3690 and comparable device classifications are included in Table 1 below.

Table 1

Device Regulation	Product Code	Total Malfunctions	Total Injuries	Total Deaths	Other	Total MDRs
21 CFR §890.3690 Powered Wheeled Stretcher	INK	111	9	0	0	120
21 CFR §890.3110 Electric Positioning Chair	INO	70	79	6	10	165
21 CFR §880.6775 Powered Patient Transfer Device	FRZ	5	3	3	1	12
21 CFR §880.5500 AC-powered Patient Lift	FNG	31	35	4	3	73
21 CFR §880.5100 AC-powered Adjustable Hospital Bed	LLI	33	51	0	1	85
	OSI	265	20	4	2	291
	FNL	*	*	*	*	>500

*There are too many records (500+) to evaluate within MAUDE for the outlined time scope.

Medical Device Reports for 21 CFR §890.3690 for the previous five years indicate a comparable safety profile to similar devices that are exempt from premarket notification. In comparison to §880.6775 and §880.5500, more malfunctions were reported for powered wheeled stretchers. However, there were no deaths reported for powered wheeled stretchers in this time frame and 3 were reported for §880.6775 and 4 for §880.5500. Compared to the other product classifications above, 21 CFR §890.3690 is the only device regulation to be associated with no deaths. In comparison to §880.3110 and §880.5100, less malfunctions and injuries were reported for powered wheeled stretchers. As outlined in Table 1, greater than 90% of reports for powered wheeled stretchers are related to non-injury causing malfunctions.

FDA's Medical Device Recalls database identified one recall associated with product code INK in the last five years. The incorrect oil was used when manufacturing hydraulic jack assemblies, and as a result, 36 devices were recalled due to an increased risk of leakage or jack drift. A review of the Medical Device Recalls database identified zero recalls in the past five years for product codes INO, FRZ, FNG, and OSI. Product code LLI had 4 associated recalls and FNL had 28 associated recalls. Based on this data, the powered wheeled stretcher is not at a significantly greater risk of a safety-related product recall than comparable devices.

A query of FDA's Warning Letter database provided no instances of a warning letter issued to a manufacturer for false claims, or other activities that would render a product mislabeled per section 502 of the Act, in relation to a device cleared under 21 CFR §890.3690.

Based on the review of the FDA's MAUDE database, Medical Device Recalls database, and Warning Letter database, there is no known data to suggest that these devices have a history of false or misleading claims. Further, the devices do not have a significant history of risks associated with inherent characteristics of the device in comparison to similar devices that are exempt from premarket notification.

2. Characteristics of the devices necessary for their safe and effective performance are well established.

Safety and efficacy of the device can be demonstrated by adherence to Quality System Regulation within 21 CFR §820 and FDA recognized consensus standards. Design Controls conducted in accordance with 21 CFR §820.30 ensures appropriate standards and other device features necessary for safe and effective performance are verified and validated prior to product distribution. Table 2 includes FDA recognized consensus standards that manufacturers implement in the design and development of medical devices compliant to 21 CFR §890.3690.

Table 2

Standard	Standard Title
IEC 60601-1	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
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 10993-1	Biological Evaluation of Medical Devices − Part 1: Evaluation and testing within a risk management process
IEC 62304	Medical device software - Software life cycle processes
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 14971	Medical devices - Application of risk management to medical devices
ISO 15223-1	Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements

Characteristics of the powered wheeled stretcher are not unfamiliar to the medical device industry. Devices within 21 CFR §890.3690 share numerous, well established features with the referenced comparable devices exempt from premarket notification. A comparison of the device features is displayed below in Table 3.

Table 3

Device Regulation	Patient Contact	Electric Powered	Patient Positioning	Holds Patient Weight	Wheels/ Casters	Brake System	Contains Software	Premarket Notification
21 CFR §890.3690 Powered Wheeled Stretcher	Yes	Yes	Yes	Yes	Yes	Yes	*	Yes
21 CFR §890.3110 Electric Positioning Chair	Yes	Yes	Yes	Yes	Yes	Yes	*	No
21 CFR §880.6775 Powered Patient Transfer Device	Yes	Yes	Yes	Yes	Yes	*	*	No
21 CFR §880.5500 AC-powered Patient Lift	Yes	Yes	Yes	Yes	*	*	*	No
21 CFR §880.5100 AC-powered Adjustable Hospital Bed	Yes	Yes	Yes	Yes	Yes	Yes	*	No

*may or may not contain feature

In addition, because characteristics of powered wheeled stretchers are well established in the market, the unintentional misuse of the device is not commonly observed. The general intended use of stretchers is for transportation of a patient remaining in a horizontal position. This intended use has remained unchanged for the decades the devices have been used in healthcare facilities and healthcare professionals understand the appropriate use of the device. Further, any reasonably foreseeable misuse is evaluated and accounted for during the risk management process, per ISO 14971, and taken into consideration during device design, per IEC 62366-1. Characteristics of powered wheeled stretchers needed for safe and effective performance are well established and are common to other devices on the market that the Agency has deemed exempt from premarket notification.

3. **Changes in the devices that could affect safety and effectiveness will either be readily detectable by users or not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.**

The inherent size and intended use of powered wheeled stretchers allows for many changes in the device that could affect safety and effectiveness to be readily detectable by users if they are familiar with the previous generation. For these highly visible changes, as well as changes that may be internal to the device, safety and effectiveness will be adequately controlled by adherence to change control processes in accordance with 21 CFR §820.30 and proper risk management techniques through adherence to ISO 14971. With these controls in place, a change that does materially increase the risk of the device can be properly assessed as exceeding the limitation of 21 CFR §890.9 and require clearance under section 510(k) of the Act.

Regulation within 21 CFR §801 ensures that a medical device is properly labelled in an easily readable manner, which includes intended uses and adequate directions for use. The regulation requires that labels on a medical device be prominently displayed so that the label is conspicuous to the user. Additionally, ISO 15223-1 establishes common symbols to be used with medical device labels, labelling, and supplied information. Both 21 CFR §801 and ISO 15223-1 ensure that changes in the device that could affect safety and effectiveness are readily detectable to any user, regardless of their familiarity with the device.

Changes to devices within 21 CFR §890.3690 that could affect safety and effectiveness will be either readily detectable by users or not materially increase the risks associated with the device. If the risks of the device were materially increased due to a change, the limitations on exemptions per 21 CFR §890.9 would apply.

4. Any changes to the devices would not be likely to result in a change in the device's classification.

The intended use of 21 CFR §890.3690 is to aid those 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). All legally marketed devices of such generic type share a common intended use and fundamental scientific technology. It is unlikely that changes to a powered wheeled stretcher would result in a new device classification. This type of device has been on the market for several decades and is well characterized and understood by manufacturers and healthcare professionals.

If a manufacturer makes significant changes to the device and is no longer certain to which device classification it should be categorized, section 513(g) of the Act provides a means for obtaining the Agency's views about the classification and applicable regulatory requirements. Further, if changes to a device classified under 21 CFR §890.3690 exceed the exemptions of the device classification but do not result in a change in classification, the limitations on exemption per 21 CFR §890.9 would apply and require clearance under section 510(k) of the Act.

A review of the 510(k) Premarket Notification database demonstrates that manufacturers adhere to the requirement to file a premarket notification, in accordance with the limitations on exemption regulations. The comparable device classifications 21 CFR §880.6775, §880.5500, and §880.5100 were exempted from premarket notification on November 3, 1998 per 63 FR 59222. Following the exemption, manufacturers have diligently filed premarket notifications due to changes to devices that exceeded the exemptions of that device's classification. Two premarket notifications have been filed for 21 CFR §880.6775, two premarket notifications have been filed for 21 CFR §880.5500, and three premarket notifications have been filed for 21 CFR §880.5100 since the 1998 amendment.

Considering the well characterized and understood intended use and fundamental scientific technology of powered wheeled stretchers, any changes would not be likely to result in a change in the device's classification. In the event of significant device changes, section 513(g) of the Act and limitations on exemption, per 21 CFR §890.9, provide means for manufacturers and the Agency to ensure the correct regulatory pathways are utilized to assure safety and effectiveness.

Based on the foregoing four factors, there is sufficient evidence to conclude that premarket notification is not a necessary control to assure the safety and effectiveness of powered wheeled stretchers. In particular, the post-market data demonstrates that powered wheeled stretchers do not have a significant history of risk associated with inherent

characteristics of the device. The undersigned is requesting an amendment to regulation 21 CFR §890.3690 to exempt the classification from premarket notification.

C. Environmental Impact

The undersigned claims categorical exclusion from environmental impact in accordance with 21 CFR §25.34(b):

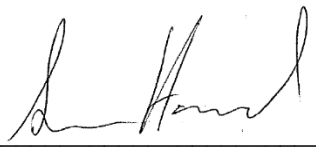
> (b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

D. Economic Impact

In accordance with 21 CFR §10.30, economic impact information shall be supplied upon the request of the Commissioner following review of the petition.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



_____(Signature)

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Sincerely,

Sean Honard

Enclosure

cc.