FDA Executive Summary

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Orthopedic and Rehabilitation Devices Panel

Reclassification of Mechanical Wheelchair Devices

Table of Contents

1. Introduction ... 3

2. Indications for Use ... 3

3. Device Description ... 3

3.1. Accessories and Components ... 4
3.2. Variability of mechanical wheelchairs ... 4

4. Classification and Regulatory History ... 4

4.1. Physical Medicine Device Classification Panel Meetings (1976 and 1979) ... 5
4.2. Purpose of the Meeting ... 5

5. Summary of Clinical Evidence ... 6

5.1. Literature Review ... 6
5.1.1. Methods ... 6
5.1.2. Studies of reported adverse events ... 6
5.1.3. General safety/adverse events ... 8
5.1.4. Studies of pressure sores and deep tissue injury ... 9
5.1.5. Bench testing comparison of wheelchairs ... 9
5.1.6. Overall Literature Review Conclusions ... 9
5.2. Manufacturer and User Facility Device Experience (MAUDE) Database ... 9
5.2.1. Recalls ... 10
5.2.2. Death Reports ... 10
5.2.3. Serious Injuries ... 10
5.2.4. Malfunctions ... 11
5.3. Clinical Summary ... 12

6. Discussion of Risks to Health ... 12

7. Mitigation of Risks to Health/Proposed Special Controls ... 13

8. Summary ... 14

8.1. Indications for Use ... 15
8.2. Reasonable Assurance of Safety ... 15
8.3. Reasonable Assurance of Effectiveness ... 16
8.4. Special Controls ... 16
8.5. Reclassification ... 16

9. References ... 18

10. Tables ... 20

1. Introduction

The purpose of this panel meeting is to discuss and make recommendations regarding the regulatory classification of mechanical wheelchair devices under the classification regulation 21 CFR Section 890.3850. These devices are intended for medical purposes to provide mobility to persons restricted to a sitting position. The Panel will also be asked to discuss whether this device type fits the statutory definition for a Class II device exempt from premarket notification [510(k)] requirements.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of mechanical wheelchair devices. The Panel will also be asked to discuss and make recommendations regarding a classification strategy for mechanical wheelchair devices currently within this classification regulation. The Panel will discuss whether mechanical wheelchairs devices should remain in Class I (requiring a 510(k) submission) or be reclassified to Class II but exempt from premarket notification [510(k)] requirements. FDA is proposing to reclassify mechanical wheelchair devices into Class II (Special Controls, exempt from 510(k) requirements). FDA is also identifying the proposed special controls that the Agency believes will provide a reasonable assurance of safety and effectiveness of the device and mitigate the risks to health. If the Panel believes that Class II exempt is appropriate for mechanical wheelchair devices, the Panel will also be asked to discuss whether the proposed special controls are adequate to provide a reasonable assurance of safety and effectiveness and to mitigate the risks to health.

2. Indications for Use

The indication for use (IFU) statement identifies the condition and patient population for which a device should be appropriately used, and for which the device has demonstrated a reasonable assurance of safety and effectiveness.

21 CFR 890.3850 states the following:
A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

This statement is representative of the indications cleared in 510(k)s for mechanical wheelchairs.

3. Device Description

Mechanical wheelchairs are a mobility aid. Proper physical motor assessment must be made of the patient's strength, range of motion, coordination, balance, posture tone and sitting position to assess the patient's ability to use a mechanical wheelchair device.

These devices consist of the following features that are integral to the function of the wheelchair:

- Frame (usually made of metal, plastic or a composite material) – These frames can be rigid or foldable (for smaller dimensions while the device is being transported).
- Seat pan/sling seat – This is the area above the frame where the patient will sit.
- Wheels – Inflatable or caster wheels
- Brakes

3.1. Accessories and Components

Mechanical wheelchairs may have accessories and components, which are listed in separate regulations and are Class I exempt, meaning that a premarket notification (510(k)) submission is not required.

A wheelchair accessory (21 CFR 890.3910) is described as "a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories include but are not limited to the following: armboard, lapboard, pusher cuff, crutch and cane holder, overhead suspension sling, head and trunk support, and blanket and leg rest strap."

A wheelchair component (21 CFR 890.3920) is described as "a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops."

Other common accessories and components include:

- Suspension for frame
- Handrims/Pushrims – Affixed to the tires to allow easy propulsion by the patient.
- Wheel locks – To prevent unintended movement of the device
- Grade-aids – Prevent backwards motion of wheelchair
- Attendant handles
- Adjustable dimensions (length, width, depth)
- Tilt-in-space – Offers recline and pressure relief to patient

3.2. Variability of mechanical wheelchairs

Mechanical wheelchairs can vary in the materials of construction and dimensions of the device. Composite materials are used to reduce the overall weight of the device, but may impact the total weight (and user mass) that the device can adequately support.

4. Classification and Regulatory History

A brief summary of the regulatory history for mechanical wheelchair devices is provided in this section.

4.1. Physical Medicine Device Classification Panel Meetings (1976 and 1979)

The Physical Medicine Device Classification Panel, hereinafter referred to as "the Panel," made preliminary classification recommendations for physical medicine devices during a series of meetings in 1976. Mechanical wheelchairs were classified in Class I (non-exempt), requiring a 510(k) submission to determine substantial equivalence.

In a 1979 meeting of the Physical Medicine Device Classification Panel, a request to exempt mechanical wheelchairs from the requirements of premarket notification records and reports and the CGMP regulations was discussed. The FDA disagreed with the request and stated that "compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of a mechanical wheelchair having defects that could harm users." (48 FR 53032)

Section 206(2) of the Food and Drug Administration Modernization Act of 1997, Section 510 (21 U.S.C.) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include a provision that most Class I devices are exempt from the requirement to submit a 510(k), with the exception of those devices that are of substantial importance in preventing impairment of human health, or any device that presents a potential unreasonable risk of illness of injury. (http://www.gpo.gov/fdsys/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf). Devices that fall into this exception are referred to as "Class I reserved" devices, and submission of a 510(k) prior to marketing is required. Mechanical wheelchairs (21 CFR 890.3850) are devices that FDA believes meet the reserved criteria in section 206 of the Modernization Act and, therefore, have been subject to premarket notification under new section 510(l) added to the FD&C Act. Refer to: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/3151.cfm.

4.2. Purpose of the Meeting

FDA is now proposing to reclassify the mechanical wheelchair devices from Class I [reserved (not exempt from 510(k)] to Class II (exempt).

FDA believes that general controls alone are insufficient to provide reasonable assurance of safety and effectiveness. However, FDA believes we have sufficient information to generate special controls that in addition to general controls may be used to provide reasonable assurance of safety and effectiveness. With the establishment of appropriate special controls, FDA believes submission and FDA review of a 510(k) is not needed to assure safety and effectiveness. As discussed in this document, FDA is considering upclassification to Class II (exempt) for mechanical wheelchair devices.

FDA will be requesting Panel feedback regarding whether mechanical wheelchair devices should remain in Class I (reserved) or be upclassified to Class II (exempt) with general and special controls.

5. Summary of Clinical Evidence

5.1. Literature Review

FDA conducted a systematic literature review to assess the safety and effectiveness of stair-climbing wheelchairs by analyzing the existing clinical literature.

The literature review sought to identify the reported adverse events associated with the use of stair-climbing wheelchairs

5.1.1. Methods

On September 19, 2013, FDA searched the published literature in PubMed using the following search terms:

- "mechanical" AND "wheelchair" OR
- "manual" AND "wheelchair"

This search yielded a total of 1362 hits. A first pass of the articles was conducted by reviewing the title of each returned hit. This was further narrowed by use of the following search terms:

- "safety" OR
- "risk" OR
- "injury" OR
- "injuries" OR

After this step, the resulting 106 articles were further reviewed. The search was narrowed by removing articles related to user capability studies rather than safety/adverse event information for the patient and user. Also removed were articles related to safety of the device while used/transported in a motor vehicle, articles related to components (cushions), and articles about repeated shoulder stress from propulsion of manual wheelchairs. While these certainly are risks for this population, they are not within the scope of the panel meeting. The resulting 23 unique articles can be grouped into the following groups:

- Studies of reported adverse events (five studies)
- Studies in which adverse events were captured (two studies)
- Studies and analyses of pressure ulcers and deep tissue injury (nine studies)
- Bench testing comparison of wheelchairs (seven studies)

5.1.2. Studies of reported adverse events

Calder, C, et al 1990

A search was carried out of death certificates from 1973-1987 with the National Injury Information Clearinghouse of US Consumer Product Safety Commission. The search identified 770 cases of all wheelchair-related deaths, including both powered

and mechanical wheelchairs. The report did not provide separate analyses of cases reported for powered wheelchairs versus those for mechanical wheelchairs. A fall was experienced by 596 users with 508 users falling out of the chair and 88 users falling in the chair, where both the occupant and chair tipped over. The report noted that environmental factors were implicated in 85 of these falls, 51 of which involved stairs. Seventy of the falls involved issues transferring the patient to or from the wheelchair. Asphyxia occurred in 58 of the cases, though not necessarily the result of falls. Thermal injuries were involved in 51 of the deaths; smoking accounted for 28 of these fatalities. Other reported causes of burns were fireplaces, fires, heating pipes, and radiators. Fracture was the most frequently reported injury associated with the death (512 reports). The second most frequent was respiratory disorder (397) followed by subdural hemorrhage (83) and cerebral contusion (65), both of which largely were the result of falls [1].

Ummat S., et al 1994

The data reported to the National Electronic Injury Surveillance System (NEISS) was evaluated between 1986 and 1990 with a total of 2066 cases reported for wheelchairs. The report did not provide separate analyses of cases reported for powered wheelchairs vs. those for mechanical wheelchairs. The article reports the major causes of accidents were falls and tips in 73.2% of cases. Other associated causes were implicated in 41.4% of cases. These other causes include furniture, stairs, toilets and bathrooms and ramps. Accidents related to transferring the patient in or out of the wheelchair were reported in 16.9% of the cases. Fractures were the most common among the fatal accidents (62.6% of fatal accidents). Contusions, abrasions, and lacerations were the most common among the non-fatal accidents [2].

Kirby, RL, et al 1995

The article summarizes the information on reportable events submitted to the FDA from August 1975 through October 1993. Files were excluded if they involved components, such as cushions. Of the 627 records identified to be related to wheelchairs, 52.8% were scooters, 24.6% were powered chairs and 22.6% were mechanical wheelchairs. Although the report noted the difference in the total numbers of reports by type of wheelchair, it did not provide separate analyses of cases reported for each type of wheelchair/scooter. The most common problems were listed below:

- Fracture (143)
- Laceration (70)
- Contusions/abrasions (63)
- Concussions/subdural hematomas (9)
- Dislocation (5)
- Dental injury (4)
- Puncture (4)
- Strain/sprain (4)
- Burns, thermal (4)
- Other (8)

This information shows that the reportable events remain similar and are inclusive of the adverse events reported in Section 5.2 [3].

McClure LA, et al 2009
Participants from 16 national Model Spinal Cord Injury System (MSCIS) facilities from April 2004 through March 2006 were recruited and were asked specific questions about the number of times within the last 6 months their wheelchair (mechanical or powered) was repaired and, for those who had at least 1 repair, if any breakdowns resulted in adverse consequences (no consequences, been stranded, been injured, missed work or school, or missed a medical appointment). A total of 2213 reported wheelchair participants were included in the study, 1364 of whom had a mechanical wheelchair. Within a 6 month period, 497 of full-time mechanical wheelchair users completed a repair and 24 were injured [4].

Worobey L, et al 2012
A sample survey of 723 people was conducted to report the incidence of wheelchair breakdown, repairs, and consequences. Patients were asked to report the number of the times in the last 6 months their wheelchair has been repaired and to indicated if the repairs resulted in: no consequence, being stranded, being injured, missing work or school, or missing a medical appointment. The study included both mechanical and power wheelchair users, and it was noted that 65% of all consequences were reported by power wheelchair users. The study found a significant increase in the number of repairs and consequences with 52.6% of full-time wheelchair users experiencing at least one repair in the past 6 months. However, there were no reported injuries as a result of these breakdowns [5].

5.1.3. General safety/adverse events

Gaal, R, et al 1997
From interviews of 109 riders, participants reported 253 incidents, 47% of which occurred with mechanical wheelchairs. Of the 119 events specific to mechanical wheelchairs, 66 of the events were “tips and falls,” 28 were “component failures,” and 25 were “other” events. The component failures for the mechanical wheelchairs were: caster (12), frame (7), rear axle & tire (6), footrest (2) and (1) miscellaneous. The other incidents that were detailed were: hit immovable object (17), van/bus lift (3) transport in vehicle (2), injury contact with chair (2), and hit by a car (1) [6].

Chen W-Y, et al 2011
A survey of participants over a three year period was held and categorized into three categories: tips and falls, accidental contact and dangerous operations. Of the 95 participants for both mechanical and powered wheelchairs, 52 reported at least one accident and 16 reported two or more accidents. Of the 50 reported accidents for mechanical wheelchairs, 49 were tips and falls, one was accidental contact (defined as a collision with an immovable or mobile object not resulting in tips or falls), and no reports were due to dangerous operation. The most common type of the 41 injuries was abrasion or laceration (29), followed by sprain or contusion, head injury, fracture

and organ injury. The most frequently injured areas were located in the upper and lower extremities, followed by head or neck injuries [7].

5.1.4. Studies of pressure sores and deep tissue injury

Multiple studies examined the mechanics and modeling of pressure ulcer formation as well as deep tissue injury [8-16]. These studies examined some of the patient factors associated with pressure sore formation. Such factors included seated pressure, seated incline, seat cushion design, and patient obesity. These studies did not specifically evaluate incidence of pressure sores in patients but did evaluate the associated biomechanics of the patient interface with the seat in different conditions to help determine the risk of pressure sore formation in various wheelchair bound populations, particularly patients with spinal cord injury (SCI). In background information provided by these reports, the prevalence of pressure sore formation in the SCI population was reported to be 33% to 50% following their trauma, 5-7% of which will require hospitalization [8].

5.1.5. Bench testing comparison of wheelchairs

Seven additional articles provided bench testing or comparative bench testing of various designs of mechanical wheel chairs [17-23]. Since these studies used test dummies, no adverse events were reported; however, the reports did evaluate several factors and characteristics of the device that are directly related to user safety. These evaluated and analyzed fatigue testing, durability, stability brake effectiveness, life-cycle testing, and tip-over mechanics. These studies noted variability in the performance of these device characteristics. The studies further noted the necessity of performance standards to provide assurance that the device meets a minimum level of performance such that user safety will be maintained despite the various wheelchair designs and materials of construction.

5.1.6. Overall Literature Review Conclusions

Falls, lacerations, sprains and fractures appear to be the most often referenced injuries. The risks identified in the literature are also identified in the adverse event information from the MAUDE database (Section 5.2, below). Bench testing reports and comparison of wheelchair devices still show variation in static stability, frame and fatigue strength, and brake effectiveness.

5.2. Manufacturer and User Facility Device Experience (MAUDE) Database

The MAUDE database is maintained by the Office of Surveillance and Biometrics at FDA. This database contains adverse events and reportable product problems with medical devices. The database was fully implemented in August 1996, and contains individual adverse event reports submitted by manufacturers, user facilities, importers, and voluntary reporters. Medical device manufacturers are required to report known adverse events as part of the general controls that most medical devices are subject to; patients and

consumers are also encouraged to voluntarily report adverse events. The reports recapped immediately below are associated with all legally marketed devices.

One does need to note the limitations to MDR reporting, including the fact that not all events are captured, since this is a voluntary reporting system. There is insufficient information to link these particular adverse events to the device use.

From the period from January 1, 2006 until August 1, 2013 there were a total of (3,492) adverse events related to mechanical wheelchairs reported. There were (8) deaths, (265) injuries, (3,209) malfunctions, and the remaining (10) were categorized as "other."

5.2.1. Recalls

From the period from January 1, 2006 until September 13, 2013 there were (12) recalls associated with seven firms. These are shown in Section 10, Table 1-Recalls on mechanical wheelchairs from 2006 - 2013.

5.2.2. Death Reports

Of the 8 death reports, six were reported from the manufacturer, one from the user facility, and one was a voluntary report. One death could be attributed to the device, two of the reports indicated an unknown cause in which the device cannot be ruled out, and five were attributed to use error. The device concerns attributed to use error were: failure to set the brakes (N=2), tip-over while turning the chair around in bathroom (N=2), fall forward while restrained (N=1) and a fall backwards (N=1). All 5 of these incidents resulted in falls with head injuries/subdural hematomas.

The death injuries attributed to an unknown cause in which the device cannot be ruled out are: head trauma/subdural hematoma (N=2), strangulation with restraint (N=1), and multiple injuries from a van accident (N=1).

The summary of the adverse events that resulted in death is shown in Section 10, Table 2- Summary of device and patient outcomes associated with death reports.

5.2.3. Serious Injuries

The MAUDE database search returned 265 serious injury reports, 29 of which were incorrectly initially assigned as "other" reports. Individual review of these 265 serious injury reports found that 110 of the reports can be attributed to the device, 44 were attributed to user error, and 111 of the reports are attributed to an unknown cause where the device could not be ruled out.

The most common patient problems from serious injuries attributed to the device are:

- Fractures (48)
- Amputation of finger tip (32)
- Cuts or Lacerations (14)

- Falls (5)
- Head injuries (2)
- Pressure sores (2)
- Unspecified injury (1)

The most common patient problems from serious injuries attributed to user error are:

- Fractures (20)
- Head Injury (10)
- Cuts/Lacerations (4)
- Unspecified injury (2)
- Falls (1)
- Pressure sores (1)
- Back injury (1)
- Never damage (1)
- Pressure sores (1)

The most common patient problems from serious injuries attributed to an unknown cause in which the device cannot be ruled out are:

- Falls (48)
- Fractures (30)
- Head injuries (12)
- Cut/Lacerations (11)
- Unspecified injury (4)
- Teeth knocked out (4)
- Pressure sores (4)
- Injuries to knee and wrist (2)

5.2.4. Malfunctions

The MAUDE database search returned (3,209) malfunction reports, 29 of which were incorrectly initially assigned as “other” reports. A sampling (317) of the malfunctions submitted were individually analyzed included a sampling of reports that were initially marked as “invalid data” or “blank.”

The most common device problems associated with malfunctions are:

- Frame/back rest broke or separated
- Wheel locks/brakes do not hold
- Cross brace broke at bolt hold
- Wheel/castor detachment
- Cross brace detaches near bolt
- Handle/grips loose or detach
- Tires defective; rubber separates from wheel

- Wheel slips or falls off
- Wheel spokes break
- Arm rest detachment
- Tilt/recline does not hold
- Seat upholstery tearing and separating
- Foot rest plate brakes or cracks
- Leg/Foot rest does not stay up
- Chrome peels off and leaves sharp shards of metal
- Casters bent from running into objects
- Chair collapsed
- Hand grips fall off
- Plastic seat guides broke, not holding up
- Detached footrest flew into MRI and hit attendant but there was no serious injury

The problems listed above were grouped for simplicity, since many were very similar. However, since multiple problem codes can be assigned for a given incident report, and it could be likely that multiple similar device problem codes were entered for the same report, the values for each incident are unknown. Therefore, values are not listed for each problem listed so as not to overinflate the actual number of incidents.

5.3. Clinical Summary

After reviewing the available literature and the adverse event information, we have identified several risks associated with mechanical wheelchairs, some of which can result in serious injury or even death. The most frequently reported injuries are falls, lacerations, and fractures. Malfunctions with mechanical wheelchairs are also numerous and are primarily related to failure or detachment of components including the frame, brakes, castors, wheels armrests. The literature indicates also that there is variability in the different characteristics and performance (e.g., durability, stability) of the available mechanical wheelchairs.

6. Discussion of Risks to Health

After considering the information from the reports and recommendations of the 1976 classification and December 12, 1979 open public meeting (48 FR 53032) for the classification of mechanical wheelchair devices, the information gathered from the MAUDE database, and FDA's literature review, FDA has identified the following risks to health for mechanical wheelchair devices:

- Instability: Instability of the device could result in the device tipping over or slipping off an edge (e.g., curb or stair), which may result in injury to the user. Use in certain environmental conditions that minimizes frictional coefficient could have the same results.

- Entrapment: The device may entrap a user or a body part, if it moves unintentionally, shifts the user into a position from which they are unable to extricate themselves, or pinches a body part against a solid object.

- Use Error: A mechanical wheelchair may be misused, if the user is not properly secured within the seat or if the device is used outside of certain environmental conditions.

- Falls/Fractures: The device is physically heavy, and if the device falls or rolls over a body part of the user or another individual (e.g., caregiver), it can result in serious injury, including fracture.

- Pressure sores: Pressure sores or bruising may result from the user experiencing jarring forces when transitioning over different surfaces or from colliding with solid objects.

- Burns: The material of the fabric of the device may not be flame retardant.

The panel will be asked to discuss the risks to health that have been identified by the FDA, whether these risks are appropriate, and whether there are additional risks to health that should be considered for mechanical wheelchairs.

7. Mitigation of Risks to Health/Proposed Special Controls

FDA believes that special controls, in addition to general controls, can be established to mitigate the risks to health identified in Section 6 above, and provide reasonable assurance of the safety and effectiveness of mechanical wheelchair devices.

When evaluating the adequacy of the special controls, it is important to understand that the FDA correlates the ability of each special control identified to mitigate an identified risk to health. Hence, FDA believes that the following special controls would provide reasonable assurance of safety and effectiveness:

1. The design characteristics of the device must ensure that the geometry and materials composition are consistent with the intended use.

2. Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:

   (i) Fatigue testing;
   (ii) Endurance testing;
   (iii) Resistance to dynamic loads (impact testing); and
   (iv) Demonstration of adequate stability of the device on inclined planes (forward, backward and lateral).

3. The skin-contacting components of the device must be demonstrated to be biocompatible.

4. Performance testing must evaluate the flammability of device components.

5. Patient labeling must bear all information required for the safe and effective use of the device, specifically including the following:

   (i) A clear description of the technological features of the device and the principles of how the device works;
   (ii) A clear description of the appropriate use environments/conditions, including prohibited environments;
   (iii) Preventive maintenance recommendations;
   (iv) Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and
   (v) A detailed summary of the device-related adverse events and how to report any complications.

6. Clinician labeling must include all the information in the patient labeling noted above but must also include the following:

   (i) Identification of patients who can effectively operate the device; and
   (ii) Instructions how to fit, modify, or calibrate the device.

The Panel will be asked whether the proposed special controls can adequately mitigate the risks to health for mechanical wheelchair devices and provide a reasonable assurance of safety and effectiveness in light of the available scientific evidence.

8. Summary

Mechanical wheelchairs devices are currently classified in Class I but require clearance of a 510(k) submission prior to marketing. In light of the information available, the Panel will be asked to comment on whether mechanical wheelchairs fulfill the statutory definition associated with a Class II (exempt) device designation. FDA believes that these devices may be more appropriately regulated as:

- Class II, meaning general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness AND

- Exempt from premarket notification [510(k)] requirements

As opposed to:

- Class I, meaning only subject only to general controls, which can include requirements to list medical devices that are marketed with FDA, good

manufacturing practices (GMPs), prohibitions against adulteration and misbranding, and labeling devices according to FDA regulations AND

- Requiring a 510(k).

Mechanical wheelchairs are not life-supporting or life-sustaining, but are for a use which is of substantial importance in preventing impairment of human health. Furthermore, FDA believes that general controls alone are not sufficient to provide assurance of safety and effectiveness. FDA believes that special controls will be adequate to ensure the safety and effectiveness of these devices.

FDA is seeking the Panel's input regarding whether the available scientific evidence supports a Class I determination or a Class II (exempt) determination with appropriate special controls.

For the purposes of classification (refer to the Regulatory Reference Sheet for additional information), FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;
2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. The reliability of the device.

Part (g)(1) of this regulation further states that "It is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is **reasonable assurance of the safety and effectiveness** of the device, if regulated by general controls alone, or by general controls and performance standards, may support a determination that the device be classified into class III."

8.1. Indications for Use

Mechanical wheelchairs are indicated to provide mobility to persons restricted to a sitting position.

8.2. Reasonable Assurance of Safety

According to 21 CFR 860.7(d)(1), "There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when

accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use."

In plain language, the definition states that a reasonable assurance of safety exists if, when using the device properly:

- The probable benefits to health outweigh the probable risks, and
- There is an absence of unreasonable risk of illness or injury

FDA will ask the Panel whether the evidence demonstrates a reasonable assurance of safety for the indications for use described above.

8.3. Reasonable Assurance of Effectiveness

According to 21 CFR 860.7(e)(1), "There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results."

In plain language, the definition states that if using the device properly provides clinically significant results in a significant portion of the target population, there is a reasonable assurance of effectiveness.

FDA will ask the Panel whether there is a reasonable assurance of effectiveness for mechanical wheelchair devices for the indications for use described above.

8.4. Special Controls

If the Panel were to recommend a Class II determination, FDA believes that the special controls proposed in Section 7, above, should be included as part of the full list of special controls. FDA proposes that special controls for mechanical wheelchairs devices would include the tests that are outlined in currently recognized standards and that are currently submitted in support of 510(k) submissions for mechanical wheelchairs.

The Panel will be asked whether the proposed special controls can adequately mitigate the risks to health for mechanical wheelchairs and provide a reasonable assurance of safety and effectiveness in light of the available scientific evidence.

8.5. Reclassification

As previously noted, FDA considers a device Class II when general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness.

In order to change the classification of mechanical wheelchairs from Class I to Class II (exempt), FDA must have sufficient information to establish special controls that can provide reasonable assurance of the safety and effectiveness that, when using the device properly:

1. The probable benefits to health from using the device will outweigh the probable risks (per the definition of a reasonable assurance of safety, 21 CFR 860.7(d)(1))

2. There is an absence of unreasonable risk of illness or injury (per the definition of a reasonable assurance of safety)

3. The device will provide clinically significant results in a significant portion of the target population (per the definition of a reasonable assurance of effectiveness, 21 CFR 860.7(e)(1))

Special controls include "the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the FD&C Act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance."

For mechanical wheelchairs, FDA believes that the available evidence suggests that special controls can be used to provide a reasonable assurance of safety and effectiveness. Special controls can be defined to address safety; for example, compliance with electrical safety standards, or adequate labeling. In addition, FDA believes that with the establishment of the special controls as proposed above, clearance of a 510(k) submission prior to marketing is not necessary to ensure a reasonable assurance of safety and effectiveness.

Based on the available scientific evidence and proposed special controls, the Panel will be asked whether a Class I (reserved) or Class II (exempt) designation is appropriate for mechanical wheelchairs "for individuals who have mobility impairments and require an assistive device for mobility."

9. References

[1] Calder, C, Kirby, RL. Fatal Wheelchair-related Accidents in the United States. American Journal of Physical Medicine & Rehabilitation. 1990: 184-190.

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10. Tables

Table 1-Recalls on mechanical wheelchairs from 2006 - 2013

Date of Recall Classification	Res Event Number	Reason for Recall	Trade Name	Recalling Firm Company Name
9/5/2006	35910	The anti-tipper as designed may not be able to bear the stress of repeated or quick loads placed on it, causing the bolt to bend or break. This could result in unintended falling with resultant injury. A more robust design has been verified and validated by the manufacturer.	KUSCHALL'S K3/K4 SERIES, MODEL AIRLITE	INVACARE CORPORATION
9/19/06	35772	He oval tie-down brackets on these wheelchairs with the travel ready option may not have had the inner edge on the bracket properly smoothed to prevent cutting of straps that might be used to tie down the chairs during transport.	SOLARA 2G MANUAL WHEELCHAIR	INVACARE CORPORATION
12/18/2007	44928	It is possible that the anti-tipper fiberglass component installed incorrectly with cross grain. Correct way is uni-directionally with the grain. Anti-tipper may fail and break and chair could tip over. Anti-tipper fiberglass component installed incorrectly with cross grain. Correct way is uni-directionally with the grain. Anti-tipper may fail and break and chair could tip over.	FREEDOM DESIGNS TRIPOD W/ANTI TIPPER MANUAL WHEELCHAIR, MODELS NUMBERS: TRIPOD, TRIPOD LT AND TRIPOD PEDIATRIC LT.	FREEDOM DESIGNS INC

8/18/2008	47781	Users are catching their fingers between the seat cradles when they try to open or close the wheelchairs, even though the wheelchairs come with the hand caution logo. The manufacturer enlarge the overall width of the seat back to slow the opening momentum of the wheelchair and to place more prominent warning labels on both sides of the seat upholstery that state "warning!!! Do not place hand or fingers between the seat frame and seat cradle when opening or closing the chair!"	MEDLINE EXCEL SHUTTLE WHEELCHAIR, 24" WIDE	MEDLINE INDUSTRIES INC
11/25/2009	52445	The handle has been breaking at a calculated weight of 65 kg which may have serious consequences (broken bones) depending on the circumstances of the break (e.g., user on ramps, hills, etc.).	KUSCHALL K JUNIOR MANUAL WHEELCHAIR	INVACARE CORPORATION
12/28/2010	51260	The stabilizer bar was inadvertently omitted during the manufacturing process.	MANUAL WHEELCHAIRS WITH TRANSIT SYSTEM OPTION	SUNRISE MEDICAL INC
09/07/2011	59305	Two bolts comprising part of the backrest assembly of TiLite ZR Series 2 and ZRA Series 2 mechanical wheelchairs have shown a tendency to fail prematurely.	TILITE ZR SERIES 2 AND ZRA SERIES 2 WHEELCHAIRS	TISPORT, LLC

01/25/2012	60180	Gunnell has received complaints that the gas cylinders used in Gunnell manual wheelchairs with dynamic recline would not hold a firm position, or as described by users, the back support or canes were spongy in the Bariatric Rehab MAC Platform Chair.	REHAB MAC PLATFORM CHAIR	GUNNELL, INC.
01/25/2012	60180	Gunnell has received complaints that the gas cylinders used in Gunnell manual wheelchairs would not hold a firm position, or as described by users, the back support or canes were spongy in the Bariatric Rehab Tough and Tilt (BTNT).	BARIATRIC REHAB TOUGH & TILT (BTNT)	GUNNELL, INC.
01/25/2012	60180	Gunnell has received complaints that the gas cylinders used in Gunnell manual wheelchairs would not hold a firm position, or as described by users, the back support or canes were spongy in the Rehab Kidster (Kidster).	REHAB KIDSTER (KIDSTER)	GUNNELL, INC.
01/25/2012	60180	Gunnell has received complaints that the gas cylinders used in Gunnell manual wheelchairs would not hold a firm position, or as described by users, the back support or canes were spongy in the Rehab Recline and Mobility (RAM).	REHAB RAM RECLINE AND MOBILITY	GUNNELL, INC.

01/25/2012	60180	Gunnell has received complaints that the gas cylinders used in Gunnell manual wheelchairs would not hold a firm position, or as described by users, the back support or canes were spongy in the Rehab Tough and Tilt (TNT).	REHAB TOUGH AND TILT (TNT)	GUNNELL, INC.
02/24/2012	61082	One Zippie TS Wheelchair was made per customer order was shipped with transit brackets for use a seat in a motor vehicle, however the chair was not configured with a back tested seat for motor vehicle use.	ZIPPIE WHEELCHAIR	SUNRISE MEDICAL (US) LLC
07/31/2012	62493	Reports of injury when the Padded Swing Away Armrest is used for full body weight. Owner's manual states that armrest is only designed for resting of forearm.	PADDED, SWING-AWAY ARMRESTS ON QUICKIE Q7, GT, GTI AND ZIPPIE ZONE WHEELCHAIRS	SUNRISE MEDICAL (US) LLC
02/04/2013	64044	The potential exists for the wheel to rotate freely despite engagement of hub brake.	SOLARA 3G CUSTOM MANUAL WHEELCHAIR	INVACARE CORPORATION

02/13/2013	64110	In May 2012 firm management removed the WC-19 verbiage and corresponding logo from the flyers on the Gunnell Rehab Series of Wheelchairs (GRSW) due to determination that the wheelchairs may not be meeting specifications of WC-19. The firm did not perform WC-19 testing to support the labeling claim. Subsequently the firm is recalling wheelchairs distributed from 11/23/10 however the firm is not recalling wheelchairs manufactured prior to that time as the firm ownership was different.	Rehab Tough and Tilt (TNT), Rehab Recline and Mobility (RAM), Rehab Kidster (Kidster)	CHENICA INC.

Table 2- Summary of device and patient outcomes associated with death reports

COUNT	MFR	REPORT NO.	YEAR REC'D	DEVICE PROBLEM	CONTRIBUTING FACTORS	PATIENT OUTCOME	EVENT ASSESSMENT
1	Sunrise Medical	2937137-2008-00012	2008	No information. Manufacturer did perform an evaluation of event.	While unattended in his room in a wheelchair, it is believed another patient tipped user over. The user was restrained at the chest, waist and feet at 45 degrees reclined when he was found. The chair was tipped sideways and he strangulated in his restraints. He was taken to the hospital with anoxic brain injury. He was removed from the ventilator 17 days later.	Death/ strangulation from restraints after chair tipped over.	Cause of event is unknown, device cannot be ruled out. The event was not witnessed and no evaluation was done of the chair.
2	Invacare	1525712-2009-00119	2009	Tipover	No information. Manufacturer received summons indicating that user fell backwards out of her chair and struck her head which resulted in death. No evaluation by the mfr. was performed.	Death/ head trauma from fall.	Cause of event is unknown, device cannot be ruled out. The chair was ordered without anti-tippers. A chair may be ordered with or without anti-tippers. Invacare strongly recommends ordering anti-tippers according to the instructional manual.

COUNT	MFR	REPORT NO.	YEAR REC'D	DEVICE PROBLEM	CONTRIBUTING FACTORS	PATIENT OUTCOME	EVENT ASSESSMENT
3	Sunrise Medical	2937137-2010-00008	2010	Seat back rest unlatched or broke while user was travelling in a van seated in the wheelchair. The incident resulted in serious injuries and death to the user.	Mfr. received photograph of the product on 05/10/2010 from an attorney. From the photos no product failure is apparent; however the bottom bracket on the right side of the backrest does not appear to be latched properly. This could be due to removing and replacing backrest but, unable to state if it was prior to the accident. The product is not expected to be returned to the mfr. for evaluation. No conclusion can be made.	Death/multiple injuries as a result of van accident where backrest broke away from the chair.	Unknown, device cannot be ruled out. Manufacturer was not able to evaluate the chair.
4.	Unknown	MW5008629	2008	None. User was in bathroom and called for assistance. When RN came, she saw the user turning around the chair which tipped over. The user struck her head and died from head injury.	The death was the result of head trauma. The device was not evaluated the mfr.	Death/ head trauma from fall.	Use Error/accident
5.	Invacare	1525712-2011-00340	2011	None. User was sitting on patio at nursing home. User did not engage breaks and rolled 4 inches off patio according to a witness. The user fell and hit her head and was transported to hospital.	The death was the result of a subdural hematoma from the fall.	Death/ subdural hematoma. User died at the hospital	Use Error/accident
6.	Invacare	[redacted]	2011	Same as #5 but report is from the user facility	Same as #5	Same as #5	Use Error/ accident

COUNT	MFR	REPORT NO.	YEAR REC'D	DEVICE PROBLEM	CONTRIBUTING FACTORS	PATIENT OUTCOME	EVENT ASSESSMENT
7.	Medline Industries	1417592-2012-00065	2012	None. User was restrained in a wheelchair unattended in her room. She apparently fell forward with the chair and was found face down. The user passed away.	The death was the result of head trauma and passed away after being admitted to the hospital.	Death/head trauma from fall.	Use Error/accident
8.	InvaMex (related to Invacare)	9616091-2013-00227	2013	Handgrips detached. User was wheeled down a ramp when handgrip detached from the back canes causing the unit to roll away and crash. No further follow-up was received.	User died from injuries sustained.	Death/ after trauma from fall	Device