

Classification Discussion: Stair-Climbing Wheelchairs

21 CFR 890.3890

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Outline

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Purpose of Meeting

Stair-climbing wheelchair devices are currently Class III and marketed through the PMA process

Do we have sufficient evidence of safety and effectiveness?
&
Can special controls be established to mitigate the risks?

Yes

Reclassify to
Class II
(510(k))

No

Remain as
Class III
(PMA)

Regulatory Definition and Description

Wheelchair Regulations

Class III	890.3890 – Stair-climbing wheelchair
Class II (510(k))	890.3860 – Powered wheelchair 890.3880 – Special grade wheelchair 890.3900 – Standup wheelchair
Class I (reserved) (requires 510(k))	890.3850 – Mechanical wheelchair
Class I (exempt from 510(k))	890.3910 – Wheelchair accessory 890.3920 – Wheelchair component

Regulatory Definition

21 CFR 890.3890 – Stair-climbing wheelchair

- *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs.
- *Classification:* Class III (premarket approval)

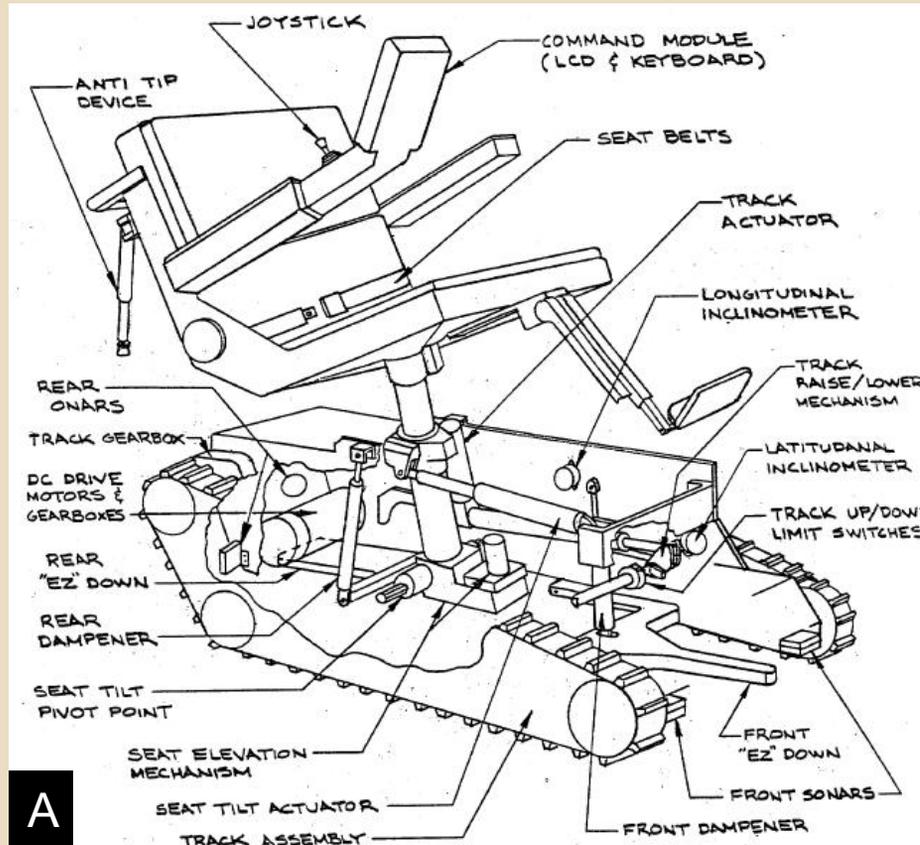
Device Description

- These devices are wheelchairs that allow the occupant to ascend and descend stairs while remaining in the device
- The devices adjust the angle of user relative to ground and allows the user to not fall out of the seat and grip the stair rail

Additional features include:

- Ability to traverse over obstacles
- Ability to traverse over rough terrain
- Shift center of gravity

PMA Approved Devices



(A) ACCESS (P900050)

(B) iBOT (P020033)

Features/Components

Device functions as both powered wheelchair (operation on smooth terrain) and allows user to ascend/descend stairs

- Microprocessor controller
- Seat elevation
- Tilt and Recline
- Battery indicator
- Speed control

Approved Indications for Use

ACCESS (P900050) - Approved June 27, 1991

The ACCESS Mobility system is a powered wheelchair with a stair-climbing capability that is designed for use by a temporarily or permanently mobility impaired individual.

iBOT (P020033) - Approved August 13, 2003

The INDEPENDENCE iBOT Mobility System is a powered mobility device for individuals who have mobility impairments and the use of at least one upper extremity. The device is intended to provide indoor and outdoor mobility in confined spaces, at an elevated height, climb curbs, ascend/descend stairs, traverse obstacles, travel over a wide variety of terrain and negotiate uneven/inclined surfaces.

Regulatory Definition Revision

- The current regulation specifies that the mode of propulsion for stair-climbing wheelchairs is an “endless belt track”
- Other modes of propulsion may be used and FDA has approved others for stair-climbing wheelchairs
- Recommend revising definition as follows:
A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs.

Regulatory History

- Classification meetings of 1976 recommended Class III but devices were initially allowed to be marketed through 510(k) process
 - The earliest stair-climbing wheelchair devices relied on comparison to “preamendment” devices (on the market prior to 1976)
 - 6 total cleared devices through 510(k) process from 1976 - 1992

Regulatory History

- August 28, 1979 (44 FR 50497), FDA published document proposing to classify stair-climbing wheelchair devices as Class III
- November 23, 1983 (48 FR 53032) - FDA published a final rule to classify stair-climbing wheelchairs into Class III
- August 18, 1998 (63 FR 44177) - FDA issued a proposed rule to require the filing of a PMA or a notice of competition of a product development protocol (PDP) for stair-climbing wheelchair devices
- April 13, 2000 (65 FR 19833) final rule published
 - Devices currently regulated through PMA process
 - 2 devices approved through PMA process

2012 Petition

- Reclassification petition filed by DEKA Research & Development Corporation to reclassify stair-climbing wheelchair devices from Class III to Class II on October 22, 2012

Petition - Indications for Use

“A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position and is intended to climb stairs.”

Petition - Risks to Health

- Device General Performance
- EMC/EMI (Electromagnetic Compatibility and Interference)
- Software Failures
- Operator Error
- Electrical Safety
- Mechanical Failures
- Device Stability in Operation

Petition - Special Controls

- Compliance to ISO 7176-24: Requirements and test methods for user-operated stair-climbing devices
- Compliance to all 33 FDA recognized wheelchair standards
- Electrical safety-IEC 60601-1
- Compliance to risk management
- EMC testing
- Compliance to software development standards, verification & validation testing, software FMEA (Failure Mode Effects Analysis)
- Prescription
- Training
- Labeling
- Durability testing
- Stability testing

2013 Proposed Order

- FDA published a proposed order on July 10, 2013 (78 FR 35173) to reclassify stair-climbing wheelchair devices to Class II (with special controls)
- Comment period open for 90 days

Public Comments

- 299 comments received
- Comments received from consumers and other members of public associated with iBOT user (friends, family and associated caregivers) Several veterans/patient advocacy groups responded
- Comments did not include information relevant to safety, effectiveness or risks of device (only anecdotal evidence)
- Vast majority of the comments received advocated this device be classified into Class II
- One comment from a patient advocacy group “Change in classification would result in greater risk for some of our nation’s most vulnerable consumers”

Clinical Evidence

- Literature Review
- MDR (Medical Device Reports)
- Data from Approved PMA Applications
- Summary of Available Evidence

Literature Search

- Background
- Methods
- Results

Literature Review - Background

- Systematic literature review of stair-climbing wheelchairs to address the following:
 - What adverse events are associated with stair-climbing wheelchairs?

Literature Review - Methods

- Searched Pubmed using the following terms:
 - iBot
 - Stair-climbing wheelchair
- Limited literature review to:
 - Human studies
 - Published in English
- Yielded 291 unique hits
- Excluded articles unrelated to safety evaluation and unrelated to stair-climbing wheelchairs.
- Yielded 3 unique for in-depth review (all observational studies)

Literature Review - Results

- 1. Laffont et al (2008) – Study of 25 tetraplegic patients in a non FDA-approved stair-climbing wheelchair (outside US data)**
 - Indoor/outdoor circuit with simulated curbs and sloped surfaces
 - Used both stair-climbing wheelchair and powered (non-stair-climbing) wheelchair device
 - No information adverse event information reported
 - Evaluators did intervene to prevent a fall during stair-climbing on 2 separate occasions

Literature Review - Results

2. Cooper, et al (2006) – One patient evaluated iBOT in both home and community

- No adverse events, small number of malfunctions
- Faults while loading/unloading device
- Device running “rough” over pea gravel
- No falls were reported

Literature Review - Results

- 3. Uustal, et al (2004) – 20 mechanical or powered wheelchair users used iBOT in community environment**
- Complete community driving test
 - No medical treatment required for adverse events
 - Total of 5 falls:
 - 2 with mechanical or powered chair
 - 3 with iBOT (not attributed to device failure)

MAUDE

- MAUDE (Manufacturer and User Facility Device Experience) maintained by Office of Surveillance and Biometrics (OSB) at FDA
- Fully implemented in 1996
- Adverse event reports can be submitted by manufacturers, user facilities, importers and voluntary reports
- Medical device manufacturers required to report adverse events
- Not all events are captured since this is a voluntary reporting system

MAUDE Search

Searched adverse event reports from January 1, 2004 through August 1, 2013 for stair-climbing wheelchairs

MAUDE Search Results

52 adverse events and no death reports

Patient Injuries

- Fractures from falls (N=20)
- Cuts/contusions (11)
- Pressure sores (2)
- Skin rash (1)
- Bicep tendon separation (1)
- Dyspnea (1)
- Sprained ankle (1)
- Report of severe burns (1)

Device Issues

- Tip over (stair mode) (8)
- Tip over (other) (5)
- Battery charger over heating (3)
- Joystick failure (2)
- Hit by car (2)
- Leg rest issue (2)
- Loss of traction (2)

14 incidents were confirmed to have occurred while climbing stairs

ACCESS – P900050

- Performed 6 types of tests:
 - Curb tests
 - Side step tests
 - Front steps
 - 32 degree stair tests
 - Test room tests (36 degree carpeted)
 - Miscellaneous contiguous stairs (concrete)
- 9 subjects were used with 20 ACCESS systems
- 20 chairs were modified with redundant safety systems and completed tests with no failures

ACCESS - P900050 (Safety)

- No adverse events reported during clinical study
- Possible hazards as identified by manufacturer
 - Operator falls out of chair
 - Wheelchair flips over forward or backward
 - Wheelchair becomes inoperable
 - Wheelchair rolls over on its side
 - Wheelchair goes off the edge of the stairs
 - Wheelchair slides down the stairs out of controls

iBOT – P020033

- Single center trial
- 20 subjects completed clinical trial
- 18 subjects completed real-world trial
- Each real-world trial consisted of 4 weeks: 2 weeks in own device and 2 weeks in iBOT

P020033 Summary of Safety and Effectiveness

http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020033b.pdf

iBOT – P020033 (Safety)

- iBOT device fell 3 times: once in balance mode, once in standard mode and once in 4-wheel mode
- Each fall resulted in a bruise

iBOT – P020033 (Safety)

Potential hazards as reported by manufacturer:

- User pinches/crushes finger/hand in moving parts
- User falls out of product
- Product falls over either forward or backward
- Product falls over laterally (sideways)
- Product becomes inoperable
- Product goes off the edge of obstacles or stairs
- User experiences jarring forces
- User collides with obstacles
- User or product injures other people
- Assistant is injured
- User falls while attempting to climb stairs
- User falls during transfers
- Electromagnetic interference causes device malfunction
- Electrical shock
- Thermal burns

Available Evidence

- Low frequency of reported adverse events
- Identified several risks associated with stair-climbing wheelchairs
- Most frequently reported injuries are falls and fractures
- Serious adverse events did occur during stair-climbing mode or resulting from tip-over
- Testing demonstrates that devices can provide mobility and climb stairs

Classification Recommendation



Classification Definitions (Class III)

FD&C Act-Section 513-Title 360(c)(a)(1)(C): A device is in Class III if...

- Cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device **AND**
- Cannot be classified as a class II device because insufficient information exists to determine that special controls would provide reasonable of safety and effectiveness **AND**
 - Is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health **OR**
 - Presents a potential unreasonable risk of illness or injury

Classification Definitions (Class II)

FD&C Act-Section 513-Title 360(c)(a)(1)(B): A device is in Class II if...

- Because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device **AND**
- For which there is sufficient information to establish special controls to provide such assurance.

Examples of special controls include: performance standards, postmarket surveillance, patient registries, special labeling requirements, and development and dissemination of guidelines

Classification Definitions (Class I)

FD&C Act-Section 513-Title 360(c)(a)(1)(A): A device is in Class I if...

- General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device **OR**
 - Is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, **AND**
 - Does not present a potential unreasonable risk or illness or injury.

Risks to Health

FDA identified the following risks to health which are the same as those in the in the July 2013 proposed order:

- Instability
- Entrapment
- Use Error
- Falls/Fractures
- Battery/Electrical/Mechanical failure
- Pressure Sores
- Burns
- Electric Shock
- Electromagnetic Compatibility & Interference

Panel Question

The panel will be asked to discuss the risks for stair-climbing wheelchairs including if FDA has identified a complete and accurate list of risks and if any other risks should be included or removed from this list.

Reasonable Assurance of Safety

- 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 probably 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.

[21 CFR 860.7(d)(1)]

Reasonable Assurance of Effectiveness

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.

[21 CFR 860.7(e)(1)]

Safety and Effectiveness

- Frequency of adverse event information is very low
- Adverse event information identified in MAUDE encompasses risks identified in literature
- Most frequently reported injuries are falls and fractures.
- Available evidence demonstrates that the device provides mobility to those in a seated position and can climb stairs.

The panel will be asked whether available evidence supports a reasonable assurance of safety and effectiveness for stair-climbing wheelchairs.

Special Controls

- If the Panel were to recommend a Class II determination, FDA believes that the special controls proposed below should be included as part of the full list of special controls:
 - Design characteristics ensure geometry and materials composition are consistent with intended use
 - Biocompatibility testing
 - Software design, verification and validation
 - Electrical safety, electromagnetic compatibility and interference (EMC/EMI) Testing
 - Battery safety and longevity
 - Flammability
 - Patient and clinical labeling

Special Controls

Performance testing demonstrating adequate mechanical performance under simulated use conditions and environment including:

- Fatigue
- Endurance
- Resistance to dynamic loads (impact)
- Effective use of braking mechanism and how device stops in case of an electrical brake failure
- Adequate stability of device on inclined planes (forward, backward and lateral)
- Safely ascend/descend obstacles (stairs, curbs)
- Use device adverse temperature and following storage adverse temperature/humidity conditions

Panel Question

The panel will be asked whether the proposed special controls mitigate the risks to health for stair-climbing wheelchair devices and provide a reasonable assurance of safety and effectiveness in light of the available scientific evidence.

Conclusion

- FDA believes that the available evidence suggests that special controls can be used to provide a reasonable assurance of safety and effectiveness
- FDA believes that the device may be classified to Class II with Special Controls and regulated under the 510(K) process

Based on the available scientific evidence and proposed special controls, the panel will be asked whether a Class II or Class III designation is appropriate for stair-climbing wheelchairs for the indications of “providing mobility to persons restricted to a sitting position and intended to climb stairs.”



Thank you!