Clinical Evaluation Summary

1. General Details

1.1. Purpose

This Report (CER) is intended to demonstrate that SoftWheel™ complies with the relevant MDD Essential Requirements covering safety and performance. In addition, the report references the product propose, performance and effect on its market and users.

1.2. Scope

The document evaluates the clinical data providing evidence that SoftWheel™ confirms with the Medical Device Directive in terms.
This document describes the SoftWheel™ technology in general and discusses the clinical aspects of its operation.

Product Identification

2. Clinical Introduction and State of the Art

2.1. Whole Body Vibration (WBV)

Whole-body vibration (WBV) is the vibration transmitted by supporting surfaces to the entire human body. Multiple studies have shown a correlation between WBV and injuries in the trucking, construction, and farming industries [1]. The primary health concern associated with WBV is lower back pain [2].

2.2. WBV in wheelchair users

Since a wheelchair is a surface supporting the entire weight of the body, it is capable of transmitting vibrations to the person sitting in the chair. In particular, exposure to whole-body vibrations exceeding standards set for industrial occupations has been documented during wheelchair use [6]. Vibration and shocks may impact the condition of the spinal column and produce back pain [7], and the prevention of these elements is relevant to wheelchair users.
wheelchair users with spinal cord injuries are particularly vulnerable to the negative effects of vibrations [8].
long-term wheelchair use may lead to secondary injuries as a result of exposure to shock and vibrations

2.3. Suspension systems in Wheelchairs

Different types and components of suspension systems are commercially available. Vibration studies conducted on a range of suspension elements have found that they are capable of reducing the vibrations transmitted to the wheelchair-user. The performance of the suspension elements was noted to be dependent on the relative orientation of the suspension elements with respect to the direction of the vibratory excitations [10].

3. Device Description

3.1. Overview

SoftWheel™ is a specialized wheel designed to be installed in any regular wheelchair, and provides a symmetric absorption system that is able to decrease vibrations, thus minimizing the risk of injuries to the neck and lower back.

Vibration reduction is achieved by the SoftWheel™ in-wheel suspension technology. With its symmetric design, it provides suspension that is independent on the orientation of the chair or the angle of the obstacle. This unique capability deals with the major limitation of existing suspension systems, most of them embedded in the wheelchair frame and cushions.

Figure 1 – the SoftWheel™

3.2. Functionality

The function of SoftWheel™ is mostly measured in vibration reduction in different frequencies. This is achieved by three spring-damper suspension units installed symmetrically in the wheel. The addition of dampers along with the springs causes suspension to be activated only when needed and remain rigid on flat terrain, unlike the existing suspension wheels available.

The suspension arms and the hub shift to absorb the shock when an obstacle or rough terrain is encountered, and then immediately return to the center of the wheel after passing the obstacle.

This leads to a smoother, more stable ride for the user and makes it easier to propel on all terrains.

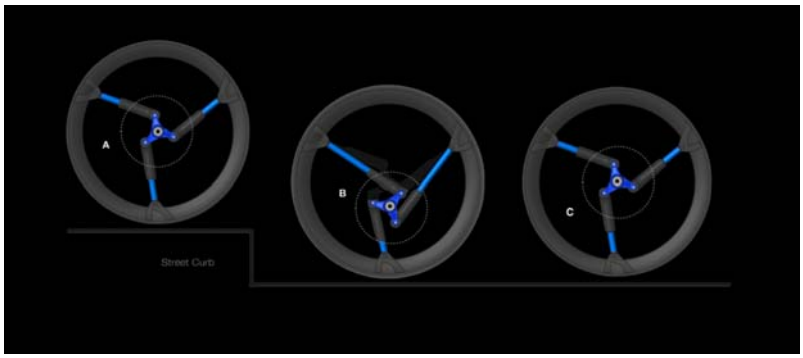

Figure 2– Illustration of the shift in the center of the wheel when shock is absorbed

4 Equivalent Device

4.1 Equivalent Device Comparison Table

Feature	Loopwheel™ by Jelly Products Ltd.	SoftWheel™ by SoftWheel Ltd.
Intended Use	Loopwheels™ are intended to improve comfort and mobility for people who use a manual wheelchair. Loopwheels™ are wheels with integral suspension designed for use as an accessory to a manual wheelchair with the purposes of (a) making it easier for a person in a manual wheelchair to pass over uneven surfaces (b) reducing the jolting and vibration felt by the person using a manual wheelchair.	SoftWheel LTD. has developed an innovative adaptive in-wheel suspension system that effectively absorbs the shock, while increasing energy efficiency. The In-wheel Suspension system consist of 3 suspension arms which are built inside the wheel rim, equidistant around a central hub. It is designed to keep the arms rigid on flat terrain, and only when encountering obstacles, they compress to absorb the shocks. After impact, the suspension arms reset quickly, and rapidly resetting, ready to absorb another shock immediately. The unique structure of the suspension mechanism enables a symmetric 360 Degrees Suspension, absorbing shocks from every direction. The SoftWheel innovative wheels were found to be effective, durable and safe. User

Feature	Loopwheel™ by Jelly Products Ltd.	SoftWheel™ by SoftWheel Ltd.
		experience suggests the wheels have the potential to reduce pain for riders' back, neck and shoulders. Softwheel's shock absorption can also enable the user to propel forward more easily, while investing less energy in the push, leading to less fatigue.
Indications for Use	Loopwheels are indicated for disabled adolescents and adults who weigh between 50 kg and 120 kg and use a manual wheelchair.	SoftWheels are indicated for adolescents and adults who weigh 38-136 kg (85-300 lbs.) and who use a wheelchair.
Materials used	Springs - carbon fiber composite material. Rims, rim connectors, hub and hub connectors - die-cast aluminum.	Hydraulic and pneumatic damper – oil, nitrogen, Aluiminium, Rims, rim connectors, hub and hub connectors - die-alloyed aluminum. And stainless steel
Size and weight	24 inch: 1.8kg 25 inch: 1.85kg *Weight without tires and no push rim	24 inch: 2.1kg 25 inch: 2.2kg
Vibration reduction mechanism	Three carbon fiber springs around a central hub	Three piston dampers around a central hub
CE-Mark approved	Yes	Yes

1. Summary of the Clinical Data and Appraisal

2. Clinical Data Analysis

2.1. Introduction

SoftWheel™ has been marketed for over three years. During that time clinical data supporting its safety and performance has been accumulated. Other devices with similar

purposes are also being marketed and investigated, and the large scale use of wheelchairs has brought about many studies that aim to find possible improvements for their users.

2.1.1. Safety (MDD Essential Requirement 1)

Since the SoftWheel™ does not supply treatment, but rather are an aid to mobilization; safety features are mostly related to the problem SoftWheel aims to solve – WBVs.

A study conducted according to ANSI/RESNA standards showed that differences existed in the force and moment data exerted on a manual wheelchair when testing on a simulated road course and during a home trial as compared to the ANSI/RESNA standards testing. This study also showed that manual wheelchair users propelling over a simulated road course do experience vibrations that could be considered dangerous [12]. This safety issue is addressed in the performance section, as it is the performance outcome intended by SoftWheel.

According to the ISO-2631-1 standard, frequency ranges that should be accounted for when dealing with human exposure to whole body vibrations are:

1. 0.5Hz to 80 Hz for health, comfort and perception
2. 0.1Hz to 0.5Hz for motion sickness

Vibrations experienced in the natural frequencies of humans (4–15 Hz) have been shown to cause the most injuries [9].

2.1.2. Performance

A study including ten males with spinal cord injury (SCI) (5 with high spinal cord injury and 5 with low, meaning above and below the thoracic level) testing different types of wheelchairs: one rigid-frame wheelchair (Quickie GPV, Sunrise Medical) and three suspension-frame wheelchairs (Boing!, A4, and Quickie XTR), concluded that forces measured during the use of chairs with suspension were significantly lower than during the use of the standard wheelchair [6].

study including a single ‘test pilot’ (44-year-old male, 68 kg, thoracic 7–8 spinal cord

injury) compared 16 different manual wheelchairs: 4 with suspension, 4 folding, 4 rigid and 4 lightweight rigid made of Titanium [13]. The test pilot was asked to descend three different height curbs (5, 10, and 15 cm) using each of the 16 wheelchairs in a randomized order, as seat accelerations was measured with an instrumented seat plate that consisted of a 0.95 cm-thick piece of aluminum fitted with a triaxial accelerometer. These are the results:

Peak seat accelerations and peak frequency-weighted seat accelerations. Data presented as mean ± standard deviation.

Type/Model	Peak Seat Acceleration (m/s²)			Peak Frequency-Weighted Seat Acceleration (m/s²)		
	5 cm	10 cm	15 cm	5 cm	10 cm	15 cm
Suspension						
A-6S*	–19.50 ± 2.42	–41.26 ± 8.16	–68.45 ± 16.77	–8.45 ± 2.14	–16.95 ± 1.69	–23.77 ± 3.95
Barracuda†	–27.50 ± 1.92	–33.26 ± 7.62	–61.41 ± 15.98	–12.16 ± 0.88	–17.25 ± 4.06	–28.94 ± 7.97
Boing!‡	–19.50 ± 0.55	–31.66 ± 5.29	–51.18 ± 11.73	–8.87 ± 0.58	–16.47 ± 2.21	–21.28 ± 3.13
Quickie XTR§	–16.62 ± 0.55	–27.82 ± 4.54	–32.62 ± 4.54	–5.03 ± 1.18	–10.61 ± 1.57	–14.75 ± 1.16
Folding						
Epic†	–28.46 ± 5.84	–51.82 ± 12.15	–56.61 ± 7.20	–13.08 ± 4.61	–26.65 ± 5.29	–31.46 ± 6.22
Action Xtra*	–31.66 ± 3.63	–47.98 ± 9.47	–54.38 ± 11.68	–15.36 ± 1.43	–26.53 ± 4.95	–29.26 ± 3.67
Champion 1000¶	–35.18 ± 6.92	–46.38 ± 5.46	–69.41 ± 6.94	–17.79 ± 2.58	–23.29 ± 3.34	–35.53 ± 3.57
Quickie 2§	–30.70 ± 9.07	–39.98 ± 8.20	–45.42 ± 4.33	–14.17 ± 3.84	–20.06 ± 4.25	–24.67 ± 5.46
Rigid						
Eclipse‡	–21.10 ± 4.43	–36.46 ± 11.04	–58.21 ± 12.48	–8.35 ± 2.53	–16.99 ± 3.43	–23.85 ± 8.28
A4*	–33.58 ± 12.23	–46.70 ± 11.52	–59.49 ± 13.62	–14.84 ± 3.91	–20.15 ± 4.89	–33.46 ± 3.69
Quickie GP§	–31.02 ± 5.79	–47.02 ± 2.00	–61.73 ± 18.82	–12.89 ± 4.26	–23.08 ± 4.82	–29.74 ± 7.33
Top End Terminator*	–22.70 ± 9.60	–34.54 ± 4.43	51.82 ± 12.15	–8.94 ± 6.26	–14.51 ± 2.85	–23.68 ± 8.32
Rigid Titanium						
A4 Ti*	–30.06 ± 4.00	–49.90 ± 9.66	–62.69 ± 14.53	–14.53 ± 3.11	–22.87 ± 4.15	–30.89 ± 6.38
Quickie Ti§	–21.74 ± 3.84	–35.18 ± 6.29	–52.46 ± 6.65	–9.68 ± 3.19	–16.81 ± 2.04	–29.95 ± 4.09
Cross Sport Ti**	–31.34 ± 2.93	–41.90 ± 8.71	–52.14 ± 26.13	–14.72 ± 1.21	–22.43 ± 2.78	–20.01 ± 7.40
Top End Terminator Ti*	–24.94 ± 3.46	–32.94 ± 5.34	–74.53 ± 10.26	–11.99 ± 0.77	–13.61 ± 5.73	–33.98 ± 2.20

Figure 3 – the acceleration for each type of wheelchair tested

Another study including 8 men with complete compared 4 different wheelchairs: one standard rigid-frame and 3 suspension-type wheelchairs. The study determined the seat force and head accelerations experienced by manual wheelchair users performing curb descent landings with rear- suspension-type wheelchairs were lower than with rigid wheelchairs [14]. Overall, change in seat force (dF), peak upward head accelerations (Avmax), peak forward head accelerations (Ahmax), and peak backward head accelerations (Ahmin) were lower in the wheelchairs with compared with the non-suspension wheelchair.

5. Non-Clinical Data Analysis

5.1. Usability

Usability aspects for SoftWheel™ were examined and addressed through risk management activities and the User Manual
Assessment of patient experience using a manual wheelchair equipped with in-wheel suspension.
Research purpose: The purpose is to assess the safety and performance of the SoftWheel in-wheels suspension system in the routine environmental use.

Results: major differences when riding over obstacles.

Confidence during ride: major differences.

Comfort during ride: major differences.

6. Post-Market Safety Surveillance Data

Since SoftWheel™ is a class I device, and the risk posed by it is extremely low, no post market surveillance is formally documented.

No.	Adverse Event	Mitigation by SoftWheel
1	The left front wheel popped off of the transport chair, and the end-user fell sideways. There is also a screw on the back of the chair that is not centered properly. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=6653543&pc=KNN	Wheel is assembled to chair as any other wheelchair wheels. That eliminates assembly mistakes that can cause that risk.
2	The rubber came off of the rear wheel. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2930925&pc=IOR	Wheel ETRTO is according to standard. As long as the tire is the same, the risk of such to happen is very low
3	Tires are off of the wheel rim. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2929695&pc=IOR	Wheel ETRTO is according to standard. As long as the tire is the same, the risk of such to happen is very low
4	The wheel broke and the spoke snapped in half. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2929701&pc=IOR	The wheel has no spokes. The wheel passed tests according to standard. Passed institution tests such as Pittsburg at USA and TUV at Europe
5	Both of the rear wheels are 'wobbly' and the bearings are extremely noisy. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2927618&pc=IOR	The wheel passed tests according to standard. Passed institution tests such as Pittsburg at USA and TUV at Europe. Bearings are high quality and the housing is designed according to requirement.
6	The wheel lock keeps loosening up. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2927621&pc=IOR	Wheel needs to be installed to chair correct. Wheel lock is a chair component needs to be adjust to wheel properly.
7	The seat frame has cracked from using e-motion wheels. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2925961&pc=IOR	Softwheels are the solution for such a problem, as dumping the roads shocks protects the frame and the rider from impacts, fatigue, and loads.
8	The solara2g mechanical wheelchair rear wheel bearing was loose, and the corresponding tire was sliding. There was no injury alleged. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=2921341&pc=IOR	Bearing boreholes are machined according to manufacturer's instructions. QA is performed strictly. Rim size is according to ETRTO standard and tolerance.

No.	Reason for recall	Mitigation by SoftWheel
1	Weel assembly failing resulting in damaged wheels. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=130754	Wheel connection to chair is standard as any wheel of wheelchair. The issue is to be solved by correct installation of assembler
2	The potential exists for the wheel to rotate freely despite engagement of hub brake. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=115268	Wheel connection is standard as any wheel of wheelchair. The issue is correct installation by assembler

7. Assessments of Clinical Investigations

7.1. Clinical Investigation

A clinical trial was held in order to assess the performance of the SoftWheel™. Both physical measurements and participants' opinions showed that SoftWheel™ is as good if not better than the alternative. Furthermore, SoftWheel™ has been evaluated in a clinical trial at HaEmek Medical Center, Israel, to assess patient experience using a wheelchair equipped with SoftWheel™ suspension wheels, and their performance characteristics have been investigated and compared to the existing methods and devices available. The results of this trial show that both safety and performance features of SoftWheel™ are either equivalent or superior to existing devices.

Clinical trail data: Two groups ride wheels, one with SoftWheel™ and other with spoke wheels. The wheels were hidden. Questionnaire are filled every step of the trail.

Number of participants: 24.

Trail duration: 1 year.

Date of completion: Feb 2018.

These are some of the main results arising from the trial:

A participant survey held during the clinical trial demonstrated that 78% of participants felt an improvement in safety and control using SoftWheel™ in comparison with standard

wheels. Furthermore, 75% of participants replied that SoftWheel™ significantly reduces shocks, and this feeling was backed by measurements made during the trial:

The Softwheel suspension performance was measured in different frequency ranges. According to test performed in those specific frequencies there is at least a 7dB gap in favor of the Softwheel™ wheels and more than a 20dB reduction in other frequencies (11Hz for example).

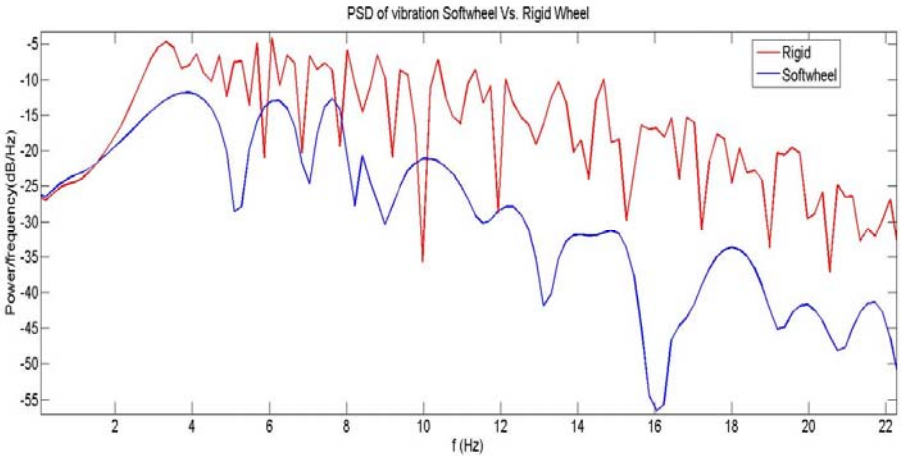

Figure 4: PSD graphs – SoftWheels compared to rigid wheel on a drop test from 15cm with 30 kg load.

Another important function is shock absorption. At a drop test, where both rigid wheels and SoftWheel™ wheels, loaded with 30kg weight, were dropped from 15cm height – it was shown that while SoftWheel's settling time (oscillations) took ~1.4 seconds, the rigid wheel took more than 4 seconds in order to settle. This is on top of achieving 50% shock reductions by Softwheel wheels [Figure 8].

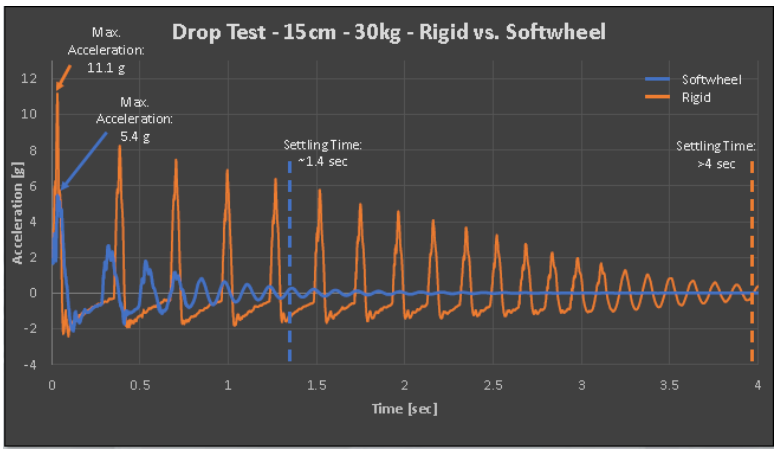

Figure 5: Drop test comparing shock and oscillation reduction by SoftWheel's wheel compared to rigid wheel

7.2. Post-market clinical follow-up (PMCF) study

Risk management activities in SoftWheel determined that a PMCF study is not necessary due to the low level of risk posed by the device. Should the device change in a way that would require a new assessment of risks, this topic will be reevaluated.

8. Assessment of benefit/risk

8.1. Device Risk Analysis

The SoftWheel™ meets all relevant safety related Essential Requirements as defined by the Medical Device Directive. The safety of SoftWheel™ has been identified and demonstrated during the risk assessment, design verification testing and compliance with applicable standards.

8.2. Advantages of SoftWheel™ (benefits)

As can be shown from the data gained to date, SoftWheel™ decreases vibrations better than the available alternatives, and provides better shock absorption. In addition, SoftWheel™ provides an improved user experience and a feeling of control and comfort.

The major advantage of SoftWheel™ is in preventing long term damage caused by WBV, including low back, neck, and shoulder pain, and increased risk of the spine and of the peripheral nervous system.

8.3. Risks

Since SoftWheel™ is intended to be used as an accessory to a wheelchair, a low risk medical device on its own; the risks associated with it are remarkably low. Nonetheless, they have been addressed during the risk management process and have been reduced as far as possible. The remaining risks, such as erroneous installation, tipping at high speeds, wheel-lock disengagement, trapping body parts etc. have been addressed in the user manual and appropriate labels.

8.4. Risk – Benefit Balance

Based on the above, a risk-benefit analysis was performed, it was concluded that:

- The risks posed by the devices are non-significant and outweighed by the medical benefit.
- The overall risk posed by the devices is non-significant and the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

9. Conclusions

The SoftWheel™ marketing history shows a satisfactory record of safety and performance that is at least as good as the state of the art.

SoftWheel's risk management process eliminated and reduced residual risks to as low as reasonably possible.

According to the available data it can be concluded that SoftWheel™ fulfills the Essential Requirements of the Directive for the intended use, that the performance and safety of the devices has been established as claimed and that the risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

10. Summary

The clinical experience gained to date with SoftWheel™ as well as supported literature review showed that SoftWheel™ is a helpful tool in preventing WBV. The use of the device is intuitive, and greatly resembles that of a regular wheel intended for a wheelchair.

The goal of this CER was to evaluate SoftWheel™ and demonstrate that the device meets the essential requirements of the Medical Device Directive (MDD) 93/42/EEC, ISO 14155 and MEDDEV 2.7.1 and sufficiently addresses the clinical risks identified in the Risk Management of the device.

This CER with its supportive documents demonstrates conformity assessment with the MDD Essential Requirements (specifically requirements 1, 3, 6, and 6a) covering safety and performance. From a clinical perspective, this CER demonstrates that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any potential adverse events, are minimized and acceptable when weighed against the benefits of the intended performance.

11. References

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