02/25/2025

Insurance Application Support

To Whom It May Concern,

Thank you for reviewing our insurance application for coverage of the Levity device. Ora Medical, as the manufacturer and distributor of Levity in Canada, is pleased to provide the following documentation to assist you in making an informed decision for your plan members:

- **Registration with Federal Entities:** Documentation outlining the approval and categorization of the Levity as a pediatric walking aid in Canada and the United States.
- **Comparative Analysis:** A detailed comparison demonstrating how the Levity meets or exceeds the specifications of approved devices such as the MyWay, Crocodile, Pacer, Buddy Roamer, and others in the same category.
- **Clinical Evidence:** Case studies and clinical evidence (included in the appendix) that illustrate the effectiveness of the Levity in pediatric rehabilitation and its benefits for children with mobility challenges.
- **Levity Flyer:** Detailed specifications and user requirements for the Levity dynamic gait trainer, highlighting its design features, foldability, and dynamic support system.

We are confident that the enclosed information clearly demonstrates the value and suitability of the Levity device for children with specific mobility needs. Should you require any additional clarification or further documentation, please do not hesitate to contact us.

Thank you for your time and consideration.

Sincerely,

Sarah Lambert, CEO & Cofounder Ora Medical

Registration with Federal Entities

The Levity gait trainer fits well within the "Paediatric Specific Walking Frame" category, as recognized by government entities. In both Canada and the United States, the Levity is registered as a “mechanical walker”, under the same category as competitive products like the Pacer, which is also covered by many insurance plans.

Canada

Since January 2023, Levity is sold in Canada as a class I, product code ITJ. In an email from Health Canada (zehra.murtaza@hc-sc.gc.ca) sent to the team (Sarah Lambert, Louis St-Pierre, Audrey Parent and Guillaume Jones) on December 9th, 2023, Health Canada approved that our device could use the PNC 89ITJ in Canada.

United States

In the United States, Levity has for product code ITJ according to the comparison to our competitor (Pacer; Avant; Ono; Salsa; Walker from 3008986539), which have ITJ as for product code.

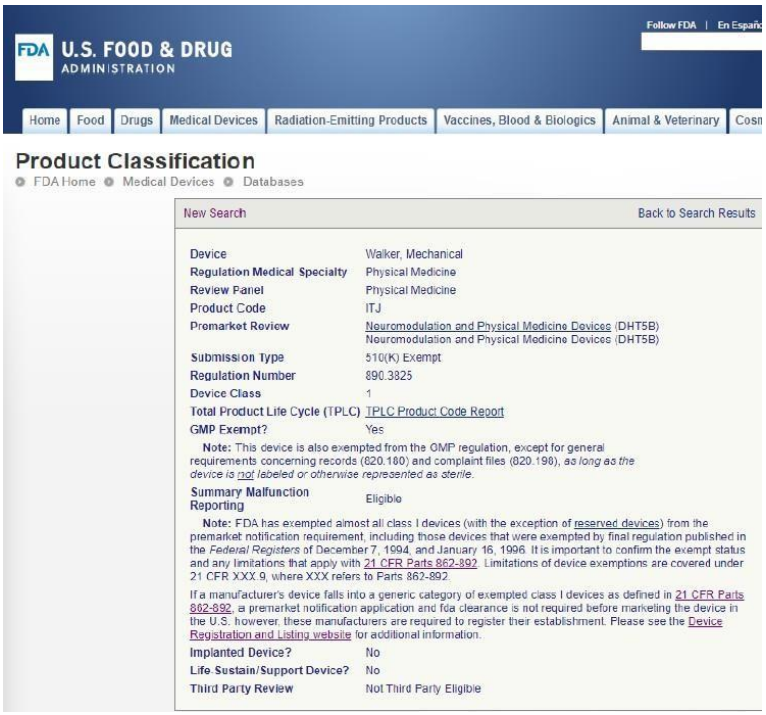


Figure 1 FDA Product Classification

This code ITJ (also known as 890.3750 Mechanical Walker) is GMP exempt in the United States (2023-07-21).

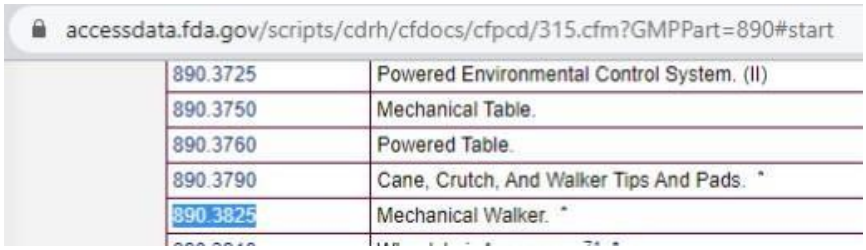


Figure 2 Regulation Number Description

Comparative Analysis

The Levity device fits well within the "Paediatric Specific Walking Frame" product category due to its design, which is comparable to other posterior walking aids. As illustrated in Figure 3, the Levity gait trainer shares many key similarities with existing products while also offering unique features that set it apart.

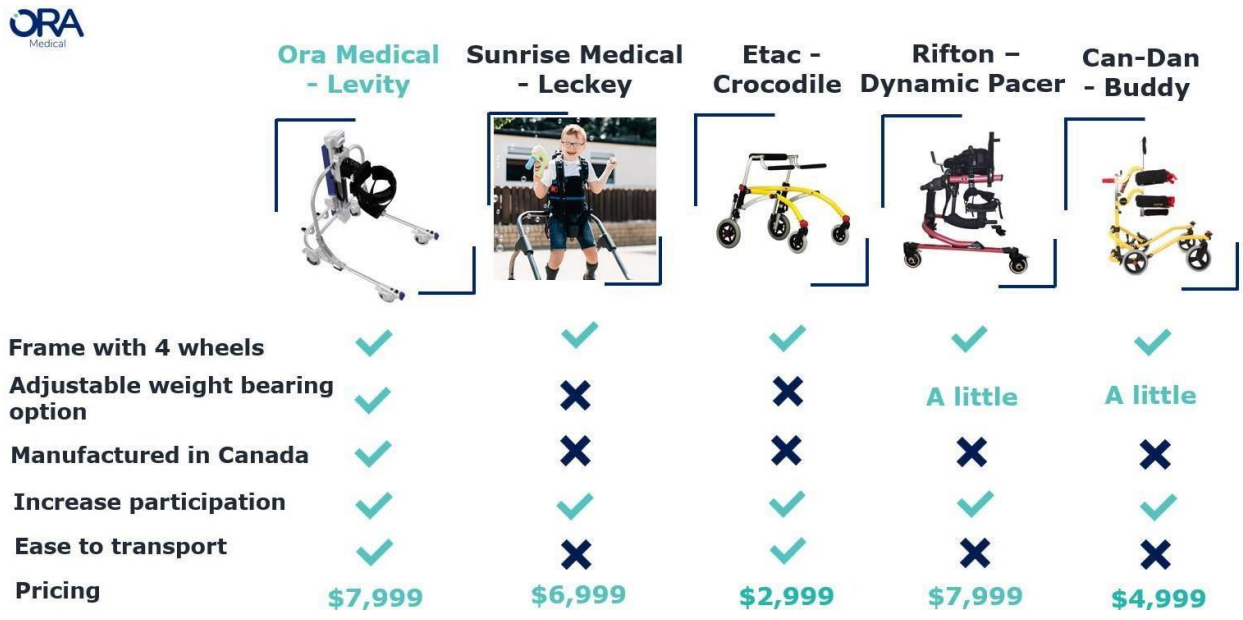


Figure 3 Levity Device Comparison

Frame with 4 Wheels: Like other devices listed under the "Paediatric Specific Walking Frame" category, the Levity dynamic gait trainer is built with a frame and four wheels, adhering to the core design of posterior gait trainers.

Adjustable Weight-Bearing Option: Numerous studies, such as those by Kurz et al. (2013) and Novak et al. (2020), have demonstrated the benefits of body-weight-supported gait training, particularly for improving walking speed and distance. Typically, body-weight support systems are either used with a treadmill or are ceiling-mounted for floor use, such as the system shown in Figure 4. These systems are voluminous and limited to short distances (length from the track to ceiling). This limits their use in clinical settings rather than everyday use.

Figure 4 Zero G System

The Levity device is designed to replicate the benefits of these systems in a compact, affordable gait trainer suitable for everyday use. To achieve this, we developed and patented a minimalistic body-weight support system using constant force springs. These rolled springs are

housed in a weight canister located at the back of the device (see green arrow in Figure 5), enabling a wide range of vertical motion (blue arrow in Figure 5).

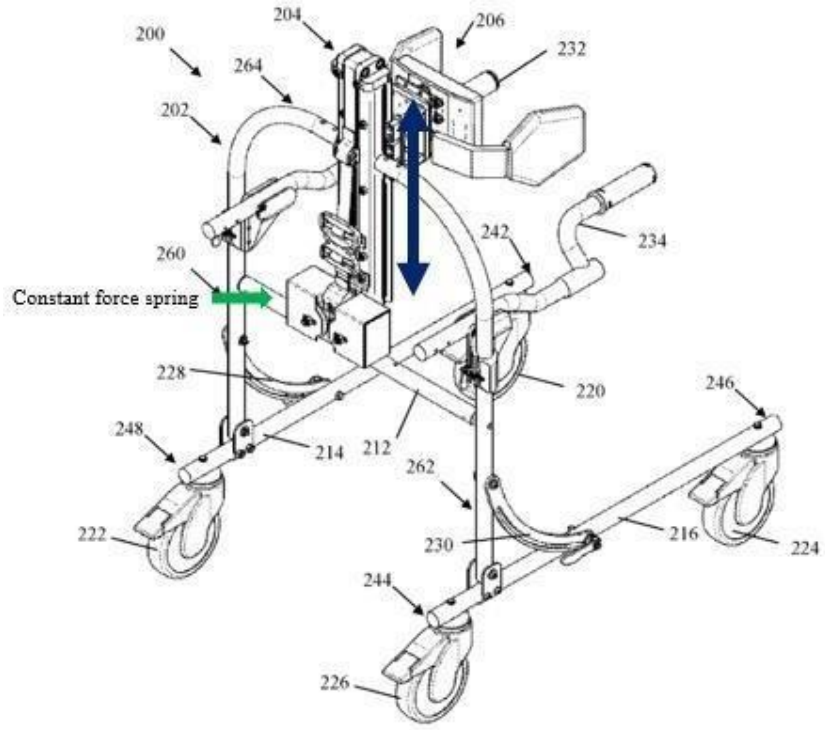
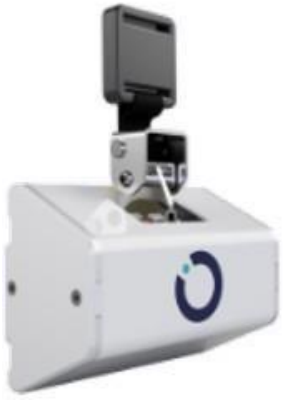


Figure 5 Levity Patent Application Publication US2024/02c1170 A1

The Buddy Roamer and Dynamic Pacer provide vertical support through their linear spring mechanisms. However, the Levity device offers a distinct advantage: it delivers a consistent amount of weight-bearing support throughout the entire range of motion along the rail. This unique feature is especially beneficial for healthcare providers who aim to promote walking with controlled, specific weight-bearing, ensuring more targeted and consistent rehabilitation outcomes.

As shown in Figure 6, the Levity comes with six different weight canisters, allowing for offloading between 8kg and 22kg.



Weight Bearing Modules
8 kg (17.64 lbs)
10 kg (22.05 lbs)
12 kg (26.46 lbs)
15 kg (33.07 lbs)
18 kg (39.68 lbs)
22 kg (48.05 lbs)

Figure c Different Weight Bearing Modules

Manufacturing in Canada: Ora Medical Inc. is the only company among the listed competitors that designs and manufactures its products in Canada. We take pride in supporting local employment and contributing to the Canadian economy through the creation of jobs.

Increased participation: Like other gait trainers, the Levity dynamic gait trainer empowers children to explore their surroundings and engage with their peers. By enhancing mobility, it facilitates greater interaction with the world around them, promoting social inclusion and participation in everyday activities.

Foldable design: The Levity dynamic gait trainer features a fully foldable design (see Figure 7), allowing it to easily fit into any car trunk or to be hung on a wall to save place. This adds significant convenience for users who need to transport their device for use outside of their primary environment or to store the device in a smaller environment. While the Crocodile Walker offers a similar feature, the Levity provides this functionality alongside its other unique benefits.

Figure 7 Levity Folded

Pricing: The Levity device is priced similarly to the Leckey MyWay and the Dynamic Rifton Pacer, which is why we are applying for comparable funding. The primary reason for this is the inclusion of a dynamic support system, which requires additional components. Despite this, we have worked to keep the cost as affordable as possible, especially when compared to high-end systems like the ZeroG, which range from $150,000 to $250,000.

We believe that our body-weight support system will significantly contribute to building a proper walking pattern, enabling children to transition away from assistive devices sooner. Our focus with the Levity is to strengthen leg muscles by allowing partial weight-bearing, which could reduce the long-term need for further devices.

Clinical Evidence

The Levity is a gait trainer intended to provide weight support during physical rehabilitation for people with walking disabilities who lack strength, good balance, or endurance, either in a clinical setting or at home.

As visually shown in Figure 8, the Levity dynamic gait trainer promotes better posture, which is crucial for improving walking patterns and overall gait stability.

Figure 8 Visual comparison between Levity and Crocodile Walker

Further studies at Rehabilitation Center Marie-Enfant (CRME) showed that a walking aid such as the Levity can allow for task-specific exercises, implementation of strength training and upper extremity function while walking.

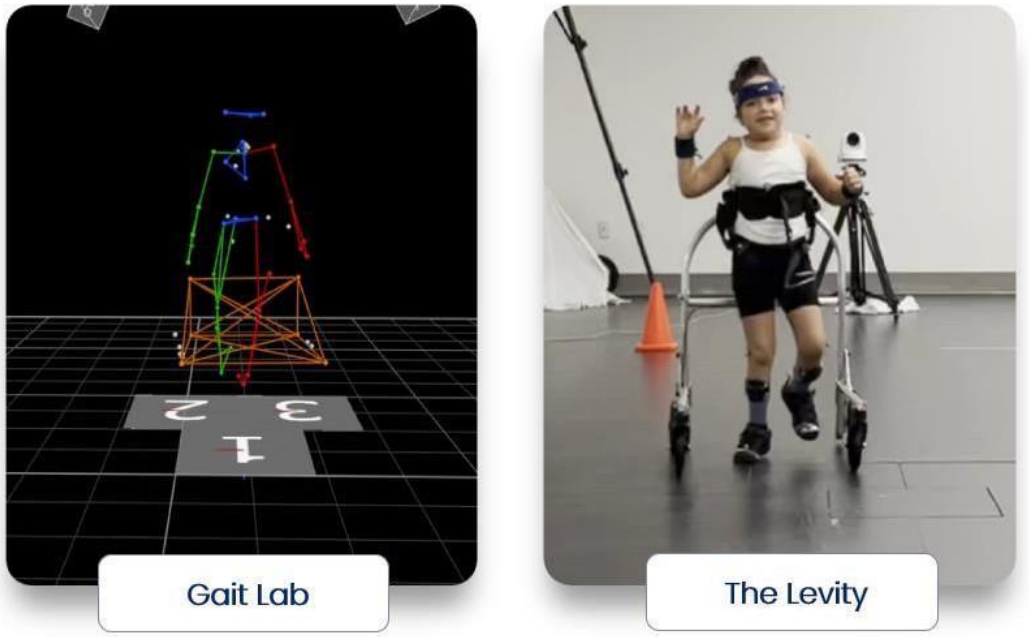


Figure 5 Levity Trial at the Gait Lab

Levity - Reference

Parent, A., Letellier, G., Lachapelle, J., Marois, P., Larochelle, J., Mohebbi, A., & Ballaz, L. (2022). Arm-free overground walking with partial body weight support in children with cerebral palsy: A case study. Gait & Posture, 97, S139-S140. https://doi.org/10.1016/j.gaitpost.2022.07.093

- **Hip kinematics suggests gait improvement with the Levity**

Levity Flyer

LEVITY

WALKING WITH YOU

A dynamic gait trainer tailored for children with walking disabilities who lack strength, good balance, or endurance

ORA Medical

How it Works

The Levity uses patented spring technology that allows for incremental offloading of the child. The device can offload six different weights: 8 kg, 10 kg, 12 kg, 15 kg, 18 kg, and 22 kg.

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Benefits of a Hand-Free Walking Aid

- Enhances participation in daily activities
- Facilitates interactions with the environment
- Promotes inclusion
- Eases interaction and play with others

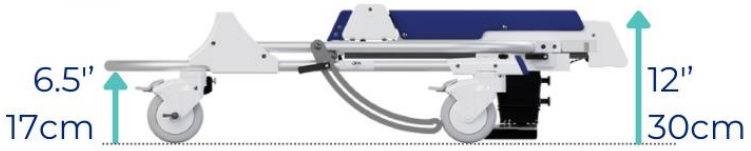
References

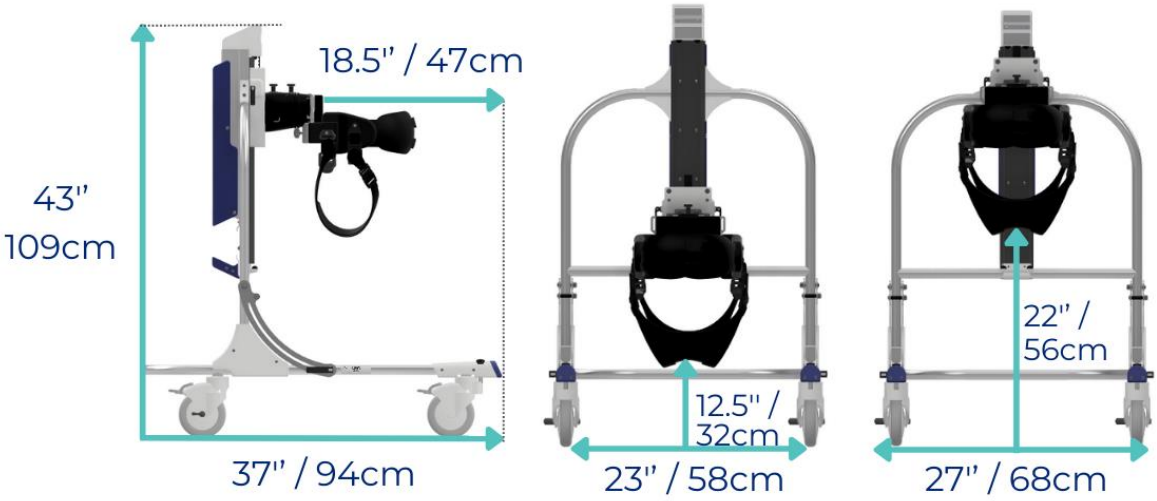
Booth et al. (2018)
Novak et al. (2019)
McKeever et al. (2013)
Paleg et Livingstone (2016)

Benefits of Training with Partial Body Weight Support

- Enhances mobility
- Improves walking distance
- Improves walking speed
- Improves posture

Levity Specifications



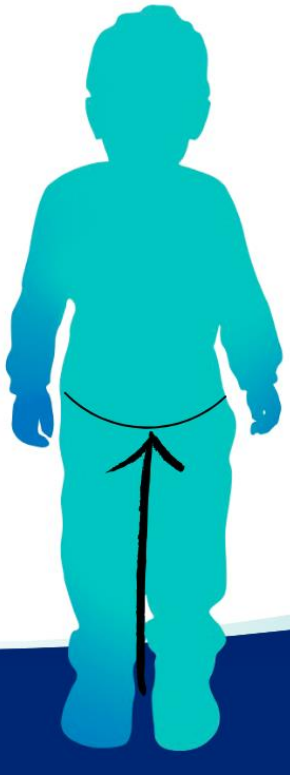


Weight of Levity:
33lbs / 15 kg
Minimum Turning Radius:
51" / 130cm

User Requirements

Weight:
25lbs - 100lbs
11.3 kg - 45.3 kg
Height:
30" - 56"
76cm - 142cm

Let's connect!



Waist Size	15" - 25" 38cm - 64cm	Small Hip Belt Small Chest Support
	22" - 33" 55cm - 84cm	Medium Hip Belt Medium Chest Support
Pelvis Height	12.5" - 15.5" 32cm - 40cm	Small Pelvic Support
	14.5" - 22" 37cm - 56cm	Medium Pelvic Support

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APPENDIX A

Evidence supporting reimbursement of the Levity

*The Levity (Ora Medical, CAN) is a **dynamic gait trainer** designed to provide **partial body weight support** for children with walking disabilities. The bodyweight support is delivered through a harness linked to an adjustable spring system, which **frees up the child's upper limbs** and facilitates interaction with its environment. Partial body weight support can be adjusted depending on the child's abilities and/or rehabilitation goals. The Levity also provides a **large vertical range of motion** allowing the child to squat and pick up object at different heights. Additional accessories can be used to increase support provided to the child.*

LEVITY DYNAMIC GAIT TRAINER

1. **Provides a partial body weight support to stand and walk**. The following benefits have been reported after training with body weight support. Similar outcomes could be observed when using a partial body weight support system every day:
    a. Allows for loading on lower limbs, which helps for muscle and bone development [1]
    b. Facilitates the development of independent walking or assist the refinement of existing walking abilities [2]
    c. Improves walking abilities when used frequently [2–6]
        - Improved walking speed
        - Improved walking endurance
        - Improved ability to take steps
    d. Improves gross motor function [3, 4, 6]
    e. Decreases fatigue [7], which allows for increasing time standing and walking.

2. **Is a dynamic gait trainer that provides support for standing and walking**.
    The following benefits on **functional abilities and health** have been reported [1, 8–10] when using a gait trainer in children with walking disabilities:
    a. Improves walking abilities
        i. Improved ability to take steps
        ii. Improved walking distance
    b. Improves gross motor abilities
    c. Allows independent mobility
    d. Increases weight bearing which helps for muscle and bone development
    e. Improves bowel function
    f. Allows to increase time being physically active
    g. Reduces passive sedentary time

The following benefits on **social abilities** have been reported [1, 10, 11] when using a gait trainer in children with walking disabilities:

a. Promotes exploration and participation
b. Increases confidence during social interactions
c. Allows for independent mobility
d. Allows for eye-to-eye interaction with peers
e. Facilitates participation with family and peers
f. Increases self-esteem and happiness

3. **Is a hands-free gait trainer,** which provides the opportunity to use the arms and hands more freely instead of relying on them for support. The following benefits have been reported [1, 9–12] when using a hands-free gait trainer:
    a. Enables to use the arms and hands to actively participate in activities
    b. May facilitates the development of more upright posture and walking using spinal musculature instead of upper limb musculature.
    c. Helps increasing attention
    d. Helps improving communication
    e. Promotes inclusion
    f. Fosters a greater sense of belonging to a family or to a peer group

4. **Allows a large vertical range of motion**, which allows children to **stand and to squat with support**. The ability to squat is essential in children's development of independent mobility [13]. Squatting ability is required to:
    a. Pick up an object on the floor
    b. Participate in several games and activities
    c. Sit on a chair and perform transfers
    d. Get out of the bed
    e. Climbing stairs

    This reflects meaningful motor activities that can be performed daily. The Levity can allow children to perform squats during certain games or certain daily life activities in a safe environment. The support provided by the Levity could allow the children to develop the ability and the strength needed to perform squats with confidence during certain activities of daily life.

Impacts on daily life, development and future

The Levity could help children to move around more freely and to participate more independently in activities with family and peers. Its hands-free design could help some children in maintaining a more upright position when participating to activities and exploring the surroundings using their hands. This can help physical, sensory and social development [14]. The vertical range of motion allowed by the Levity could help developing the ability and the strength to perform squats during certain daily life activities. By enhancing the independent mobility, the Levity could help the overall development of the child. With its support system, the Levity could allow to increase time standing and walking, contributing to reducing passive sedentary time, which may have a positive impact on muscle and bone health and bowel function. All of these factors may contribute to improve children's future health and opportunities [1].

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