CPSC Meeting Log: Otteroo

CPSC Attendees	Alex Hoehn-Saric Jana Fong-Swamidoss Anna Laitin
Date of Meeting	Wednesday, February 5, 2025
Date of Log Creation	Wednesday, February 5, 2025
Log Creator	Anna Laitin

ATTENDEES
• Tiffany Chiu, Founder and CEO, Otteroo • Emi Kamiya, Marketing Lead, Otteroo. • Kathryn Casini, Operations Lead, Otteroo Observers • Lauren Kirchner, Consumer Reports • Gabe Knight, Consumer Reports • Courtney Griffin, Consumer Federation of America • Michelle Barry, Safe Infant Sleep • Nancy Cowles

MEETING NOTES:

Participants discussed Otteroo's history and the comments that the company submitted in response to the NPR on infant neck floats. Following the meeting, Tiffany Chiu provided meeting minutes from Otteroo's meeting with FDA in December 2024. Those minutes are attached.

Meeting Minutes

Submission Number: Q242484

Submission Type: Pre-Submission

Product Name: Otteroo LUMI/child Neck Float

Submitter: Otteroo Corporation

Meeting Date/Time: December 5, 2024; 2:00 pm – 3:00 pm Eastern Time

Meeting Format: Teleconference

Date FDA Feedback was Sent: November 22, 2024

FDA Attendees:
Juliet Bottorff, PhD – Lead Reviewer, Acute Injury Devices Team
Heather Dean, PhD – Assistant Director, Acute Injury Devices Team
Kristen Gill, OTD – Lead Reviewer and Human Factors expert, Acute Injury Devices Team
Amanda Morrow, MD – Clinical expert, Neurodegenerative Devices Team
Vivek Pinto, PhD, MBA – Director, Division of Neuromodulation and Physical Medicine Devices
Julia Slocomb, PhD – Senior Lead Reviewer, Acute Injury Devices Team
Kenneth Morabito, PhD – Lead Consumer Safety Officer, Neurological and Physical Medicine Devices
Tania Reina, MBA – Assistant Director, Human Factors Team
Deborah Shoenfeld, RN, MPH – Lead Reviewer and Post-market safety expert, Acute Injury Devices Team
Sonja Sokic, PhD – Safety Signal Manager, Neurological and Physical Medicine Devices

Company Attendees:
Tiffany Chiu, CEO
Kate Casini, Operations Manager
Emi Kamiya, Marketing Manager
Rob Packard, Consultant

Detailed Meeting Minutes

Meeting Purpose:

The meeting aimed to address feedback from the FDA related to Q Submission Q242484, focusing on clarifying the Otteroo device's intended use, and user-related risk analysis (URRA). Additionally, Otteroo sought feedback on validation methods for human factors testing and design updates.

Detailed Discussion Points

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1. FDA's Position on Medical Device Classification:

The FDA and Otteroo discussed Otteroo's positioning and claims. Specific areas highlighted include:

1. **Revised Intended Use**:
    - Otteroo maintains a user's head in a stable, midline position above the water, allowing for free movement in a gravity-reduced environment.
2. **Claims and Benefits**:
    - FDA and Otteroo discussed how specific claims and intended use determine whether a device is classified as a medical device. FDA agrees that a claim regarding the device's ability to stabilize the head in a midline position is sufficient to classify it as a medical device based on its intended use to affect the structure and function of the body.
    - FDA emphasized that any additional claims suggesting therapeutic benefit (e.g., improving joint health or supporting motor planning) would require clinical evidence for validation.

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2. Feedback on Safety and Risk Mitigation Features:

Otteroo presented updates to the device, focusing on reducing submersion risks.

1. **Design Updates**:
    - Addition of Velcro straps on the inner portion of the ring to maintain structural integrity, even if partially deflated.
2. **FDA Response**:
    - Applauded the proactive approach to addressing risks but emphasized that design updates do not eliminate critical task validation requirements.
    - Suggested identifying design changes as risk controls intended to reduce use errors and to validate those risk controls through robust human factors testing.

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3. Human Factors Validation and URRA:

FDA highlighted the importance of ~~addressing~~ correctly identifying critical tasks ~~for safe use~~, emphasizing ~~areas where risks could lead to harm~~ the accurate evaluation of the potential hazards and clinical harm.

1. **Critical Tasks**

    - FDA reiterated the written feedback related to critical tasks, and provided clarification regarding how critical tasks are identified in the URRA.

~~1. **Identified by FDA**:~~
    - ~~Ensuring proper inflation of the device.~~
    - ~~Securing the Velcro straps appropriately.~~
    - ~~Supervision during use (highlighted as essential but difficult to validate directly).~~
2. **Validation Methods Proposed by Otteroo**:
    - Observational studies where participants demonstrate device setup and use with a manikin.
    - Knowledge-based questions at the end of testing to assess user understanding of key safety information.
3. **FDA's Recommendations**:
    - FDA did not provide further recommendations, but rather clarification of the written feedback.
    - FDA clarified that risk mitigations do not change the severity of the harm or potential harm

itself of the critical task.
- FDA noted that Human Factors validation testing is to be completed on the final device design.
- ~~Human factors validation must focus on identifying use errors and confirming user adherence to critical tasks.~~
- ~~Validation should not rely solely on real-world evidence but should incorporate simulated~~

~~use scenarios as per FDA's 2016 Human Factors Guidance.~~

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4. Discussion on Dual Labeling and Broader Accessibility:

Otteroo expressed a desire to make the device accessible for both therapeutic and general use.

FDA Guidance on Dual Pathways:

- During discussions on Human Factors Validation testing, the topic of whether the Otteroo device should be classified as OTC or Rx was raised. FDA indicated that the Rx pathway might be ~~more appropriate.~~worth considering.
- FDA ~~confirmed that a consumer version intended for general use would require separate labeling and claims and~~ encouraged Otteroo to seek ~~informal~~ further feedback if the company decides to pursue both an Rx version and a consumer version, rather than just an OTC version.

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5. Real-World Evidence Discussion:

Otteroo highlighted that over **450,000 units sold** with only two reported incidents indicate strong real-world evidence of safety.

1. **FDA~~'s Stance~~**:
    - Real-world evidence can inform the URRA, ~~-~~but is not ~~a~~ substitute for a human factors validation study.
    - ~~Human factors validation must identify **potential use errors** proactively, even if no adverse events are reported.~~
    - ~~o~~ A URRA is essential to ensure that all potential use hazards/risks involved in using your product (even if no adverse events have yet been reported) have been considered and appropriate risk mitigation controls have been identified.
2. **Examples Provided by Otteroo**:
    - Two adverse events involved parental negligence, not direct device failure.
    - ~~FDA clarified that even if adverse events are rare, risk mitigation measures must be validated systematically.~~
    - FDA clarified that since the probability and/or detectability are difficult to estimate accurately, you should use severity level *only* to determine critical tasks. Therefore, even if a potential error is considered rare, this does not alter the need to conduct human factors validation testing as outlined in the guidance

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6. Action Items and Next Steps:

Otteroo's Commitments:

- Update URRA and human factors protocol to reflect FDA's feedback on correctly identifying critical tasks ~~and scoring~~.
- Submit revised clinical study protocol and indications for use for review.

FDA's Commitments:

- ~~Continue supporting Otteroo with unofficial guidance where possible.~~FDA will continue to provide feedback as requested through the pre-submission process and provide unofficial help where possible.