FDA is committed to ensuring digital accessibility for people with disabilities. We are continually improving the user experience for everyone and applying the relevant accessibility standards. At the time of initial posting on **December 16, 2025**, the attached **presentation** may not be fully accessible to users using assistive technology. A fully accessible version of the **presentation** is in preparation and will be posted as soon as it is ready. We regret any inconvenience that this may cause our readers.

Please let us know if you encounter accessibility barriers by contacting **Evella Washington at: Evella.Washington@fda.hhs.gov**

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About us:

We are a small early-stage company working to commercialize our first product.

Our Experience:

Medical device innovation is alive and well, and the FDA is engaged and helpful, moving innovative devices forward even if it requires more interaction and discussion about indications for use, populations at risk, and meeting statutory requirements.

GEARED POWER™ BioTech

BioGuard UVC™

Our Product:

- Award-winning transformative technology[1]
- Congressional support for military use in H.R. 4016 and BARDA in S. 2587 appropriations bills[2]
- Potentially market dominant in healthcare settings where pathogenic risks are elevated
- Possible candidate for inclusion in the Strategic National Stockpile[3]

1. Awarded 2025 Leader in Life Sciences! By NJMEP, see winners
2. https://appropriations.house.gov/news/press-releases/committee-approves-fy26-defense-appropriations-act
3. https://aspr.hhs.gov/SNS/Pages/default.aspx

GEARED POWER™ BioTech

BioGuard UVC™

Working with the FDA:

- We have taken a novel approach to respiratory infection control:
  - Inactivate pathogens in the exhaled breath of infected individuals – or, source control
- The FDA recognizes its potential, and is working with us to address potential deficiencies in our application related to statutory requirements:
  - The population defined in the Indications for Use is the infected patient (pathogen-reservoir)
  - While the population at risk is not just the patient, but everyone in the room (the susceptible hosts)
  - The Breakthrough Device statute seems to have been written to require the population at risk to be the patient

GEARED POWER™ BioTech

BioGuard UVC™

Why is this challenging:

Our novel approach to the respiratory infection control problem involves:

- Non-Filtered protection – unlike other PPE, standard testing for proof of efficacy do not apply
- Focus on Public Health – preventing pathogens from becoming environmental contaminates (protecting "everyone in the room"™ rather than just the patient)
- Boosts natural immunity by allowing safe, mucosal exposure to inactivated pathogens
- Pathogen agnostic – while the statute for Breakthrough Device Designation requires a specific disease to be identified

Note: Claims have not yet been FDA cleared.

FDA responsiveness:

- We utilized DICE, and they were excited about the device's potential
- The FDA's responsiveness has been encouraging
  - Same day emails
  - 10 day response to our eSTAR application
  - Interactive Review status
- This advisory committee on Germicidal UV Medical Devices
- Current status: Breakthrough Device Designation is pending

Comments to Committee:

- We are proud to be working with the FDA to obtain clearance for BioGuard UVC™
- We are also grateful for the special consideration afforded to startups navigating the De Novo process, including the Early Payor Feedback Program
- We believe BioGuard UVC will transform respiratory infection control, therefore it is of strategic importance that the FDA continues to receive program funding
- We believe consideration should be given to allow the FDA operational discretion to expand such programs to include future innovations that might not have been anticipated at the time of the writing of guiding statutes.
- *Thank you* for this opportunity.