

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		<small>DATE(S) OF INSPECTION</small> 8/26/2025-8/27/2025 <small>FEI NUMBER</small> 3007048062	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Elizabeth S. Lightbody, President			
<small>FIRM NAME</small> Lightbody Medical Technologies Inc dba Artemis Surgical		<small>STREET ADDRESS</small> 101 Tower Dr	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Burr Ridge, IL 60527-5779		<small>TYPE ESTABLISHMENT INSPECTED</small> HCT/P Distributor	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>Incoming HCT/Ps were not evaluated for the presence and significance of microorganisms and not inspected for damage and contamination.</p> <p>Specifically,</p> <p>You failed to document the activities performed for verifying if a product should be accepted, rejected, or placed in quarantine upon receipt of shipment from the manufacturer and/or owner. You failed to review manufacturing and tracking records pertaining to HCT/Ps to verify that release criteria were met before distribution of HCT/Ps. You failed to document by a responsible person and record the date that release criteria of HCT/Ps were acceptable for release before distribution.</p> <p>Since 2023 you have distributed approximately (b) (4) HCT/P human amniotic, membrane, bone, cartilage, ligament, skin, tendon, and umbilical cord tissue.</p>			
AMENDMENT 1			
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Zoey A Trombley, Investigator		<small>DATE ISSUED</small> 9/18/2025
	<div style="text-align: right;"> <small>Zoey A Trombley Investigator Signed By: Zoey A. Trombley -S Date Signed: 09-18-2025 09:06:16</small> X </div>		

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."