

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION										
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 11/11/2025-12/3/2025* FEI NUMBER 3015422213								
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Gale H. Thorne Jr. , CEO										
FIRM NAME ASEPTIKITS, LLC	STREET ADDRESS 101 N 700 W									
CITY, STATE, ZIP CODE, COUNTRY North Salt Lake, UT 84054-2735	TYPE ESTABLISHMENT INSPECTED Specification Developer									
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.										
<i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>										
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Procedures for design control have not been established. Specifically, your firm currently uses procedure SOP: 200, New or Changed Product Project Management, Revision B, dated 6/27/2024, to control design developments and changes. However, your firm has not established and maintained adequate design control procedures to ensure that device design requirements are appropriately defined, verified, validated, and approved prior to release to production. During the inspection, the firm's Executive Vice President/Quality Representative stated that, to the best of his knowledge, the firm does not have documentation demonstrating implementation of design planning, design input, design output, design verification, design validation, or design transfer activities for the PALA product family. Since your firm's establishment in February 2019 and through 14 November 2025, your firm has sold the following quantities of the noted medical devices: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 33%;">Product</th> <th style="width: 33%;">Launch Date</th> <th style="width: 33%;">Total Units Sold</th> </tr> </thead> <tbody> <tr> <td>PALA 8</td> <td>5/11/2021</td> <td rowspan="2" style="text-align: center; vertical-align: middle; font-size: 1.5em;">(b) (4)</td> </tr> <tr> <td>PALA 12</td> <td>11/9/2020</td> </tr> </tbody> </table>			Product	Launch Date	Total Units Sold	PALA 8	5/11/2021	(b) (4)	PALA 12	11/9/2020
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PALA 14		7/24/2024	(b) (4)
OBSERVATION 2 A device master record has not been adequately maintained. Specifically, your firm has not established and maintained procedures to ensure the creation, control, and maintenance of a Device Master Record (DMR) for each medical device designed and marketed by your firm. During the inspection, the firm's Executive Vice President and Quality Representative provided incomplete DMR records for the PALA products. Your firm has documented device specification drawing, including labeling, but lacks production process specifications, packaging specifications, and quality assurance procedures to ensure that each device is manufactured according to approved specifications and processes. The firm's Executive Vice President and Quality Representative stated that to the best of his knowledge the firm does not have additional DMR documents for its PALA products.			
OBSERVATION 3 Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established. Specifically, your firm's procedure SOP 201, Purchasing Controls, Revision A (dated 11/1/2025) is inadequate in that it does not define methods for evaluating suppliers, contractors, and consultants based on their ability to meet specified requirements, including quality requirements. In addition, the procedure does not establish requirements for the type and extent of control to be exercised over product, services, suppliers, contractors, and consultants based on their evaluations. The firm's Executive Vice President/Quality Representative stated confirmed SOP 201 dated 11/1/2025 has been your firm's only procedure for the evaluation and control of suppliers. Since your firm's establishment in February 2019 to 10/31/2025, your firm did not have any procedures in place or perform these activities			
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to ensure suppliers continued to meet specified requirements. As a result, your firm has not adequately performed evaluations or implemented controls to ensure that suppliers providing components—including critical components such as the sterilizing filters—or services that may affect the quality of finished devices are capable of consistently meeting specified quality and regulatory requirements. Your firm's Approved Supplier List (ASL) identifies a total of (b) (4) suppliers, of which only (b) (4) has undergone a documented audit.			
OBSERVATION 4 Procedures for finished device acceptance have not been established. Specifically, your firm maintains a Quality Agreement with the contract manufacturer, signed 10/24/2025, that includes requirements for product release activities. However, your firm has not established or implemented procedures to verify that finished devices conform to specified requirements prior to release and distribution. Product acceptance activities and release decisions are performed entirely by the contract manufacturer, with no documented oversight, review, or approval by your firm. Your firm's Executive Vice President and Quality Representative stated that, for its PALA medical devices, the firm does not inspect product or review Device History Records (DHRs) prior to release to ensure the product was manufactured in accordance with specifications. Additionally, your firm does not maintain any product acceptance or nonconformance records, or release authorization documentation for its PALA products.			
OBSERVATION 5 Procedures for management review have not been established. Specifically, your firm has not established and maintained procedures for conducting management reviews of the quality system at defined intervals and with sufficient frequency to ensure its continuing suitability and effectiveness. Additionally, your firm's Executive Vice President and Quality Representative stated that the firm has no management review procedure and also that it has not			
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conducted or documented formally established management reviews since the company's establishment in February 2019. OBSERVATION 6 Quality audits have not been performed. Specifically, currently your firm uses procedure SOP: 300, Quality Systems Audit Program, Revision B, Dated 5/7/2024. However, your firm's Executive Vice President and Quality Representative stated that the firm has not conducted or documented any internal quality audits since the company's establishment in February 2019. As a result, your firm has not verified through audits that the quality system is effectively established and maintained. OBSERVATION 7 The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided. Specifically, your firm, a specification developer of medical devices distributed in the United States, is responsible for submitting device identification information to the FDA's Global Unique Device Identification Database (GUDID). However, your firm has not registered or submitted the required UDI information for its devices – Pala (all configurations), ALAdrop, VitRALAT, SyriKit, (b) (4) and (b) (4) (b) (4) - to GUDID. Since your firm's establishment in February 2019 and through 14 November 2025, your firm has sold the following quantities of the noted products: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 30%;">Product</th> <th style="width: 20%;">Launch Date</th> <th style="width: 50%;">Total Units Sold</th> </tr> </thead> <tbody> <tr> <td>PALA 8</td> <td>5/11/2021</td> <td rowspan="3" style="text-align: center; vertical-align: middle; font-size: 2em; font-weight: bold;">(b) (4)</td> </tr> <tr> <td>PALA 12</td> <td>11/9/2020</td> </tr> <tr> <td>PALA 14</td> <td>7/24/2024</td> </tr> </tbody> </table>				Product	Launch Date	Total Units Sold	PALA 8	5/11/2021	(b) (4)	PALA 12	11/9/2020	PALA 14	7/24/2024
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FORM FDA 483 (09/08)
PREVIOUS EDITION OBSOLETE
INSPECTIONAL OBSERVATIONS
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Denver, CO 80225-0087
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Gale H. Thorne Jr. , CEO

FIRM NAME

ASEPTIKITS, LLC

STREET ADDRESS

101 N 700 W

CITY, STATE, ZIP CODE, COUNTRY

North Salt Lake, UT 84054-2735

TYPE ESTABLISHMENT INSPECTED

Specification Developer

ALA Drop	10/2/2024	(b) (4)
Syrikit	8/28/2025	
Vitralla	4/8/2025	
(b) (4)	10/12/2023	

***DATES OF INSPECTION**

11/11/2025(Tue), 11/12/2025(Wed), 11/13/2025(Thu), 11/14/2025(Fri), 11/21/2025(Fri),
12/03/2025(Wed)

X

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Monica L Gutierrez, Investigator
James R Montero, Investigator

Monica L Gutierrez
Investigator
Signed By: MONICA GUTIERREZ
-g
Date Signed: 12-03-2025
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Annotations to Observations Observation 1: Observation 2: Observation 3: Observation 4: Observation 5: Observation 6: Observation 7:			
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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."