DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	2/17/2026-2/20/2026
	FEI NUMBER 3041671258

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Yasha Rezaeihaghighi, Clinical Trials Research Nurse

FIRM NAME	STREET ADDRESS
Helena C. Chang, MD	710 Lawrence Expy
CITY, STATE, ZIP CODE, COUNTRY Santa Clara, CA 95051-5173	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Records of receipt, use and disposal of a device that relate to the type and quantity, dates of receipt and batch number or code mark of the device are not all accurate, complete and current.

Specifically,

A. During the study of protocol number CLP-0002 titled "Sonomotion Stone Comminution Resonance Ultrasound Pivotal Trial," the firm did not maintain complete accountability records for the investigational devices received, used, and returned. The packing slip from November 29, 2023 documented the receipt but not the disposition of the following Break Wave Therapy Probes:

(b) (4)

The Break Wave therapy probes at the firm during this inspection were:

(b) (4)

Study subject (b) (6), (b) (7)(C) used Therapy Probe (b) (4)
Study subject (b) (6), (b) (7)(C) used Therapy Probe (b) (4) and Therapy Probe (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephanie Barragan, Investigator X Stephanie Barragan Investigator Signed By: Stephanie Barragan -S Date Signed: 02-20-2026 13:43:54	2/20/2026

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Santa Clara, CA 95051-5173	Clinical Investigator

Study subject (b) (6), (b) (7)(C) used Therapy Probe (b) (4)
Study subject used Therapy Probe

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stephanie Barragan, Investigator X Stephanie Barragan Investigator Signed By: Stephanie Barragan -S Date Signed: 02-20-2026 13:43:54	2/20/2026

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."