DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	2/26/2026-2/27/2026
	FEI NUMBER 3001237826

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald D. G. Philip, President

FIRM NAME	STREET ADDRESS
Vision Chips, Inc.	27651 La Paz Rd # 500
CITY, STATE, ZIP CODE, COUNTRY Laguna Niguel, CA 92677-3917	TYPE ESTABLISHMENT INSPECTED Manufacturer

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.

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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically,

Your firm does not have a UDI for your Class II medical image management and processing system device, OBserver 7 (K022877), which was cleared on 02/05/2003. UDI requirements have been in place for your device type since September 24, 2016. Your firm currently has (b) (4) installations of your device for customers ranging from versions 7.2.00.08 Build 3 to 7.3.03.00 Build 03 with installations occurring between 06/22/2020 to 12/04/2025.

X Tyler J Chia
Investigator
Signed By: 2002402631
Date Signed: 02-27-2026 16:28:28

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Alexandria L Capuano, Investigator Tyler J Chia, Investigator	X Alexandria L. Capuano Investigator Signed By: Alexandria L. Capuano -S Date Signed: 02-27-2026 16:27:44	2/27/2026

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Annotations to Observations

Observation 1: Not annotated

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alexandria L Capuano, Investigator Tyler J Chia, Investigator	X Alexandria L. Capuano Investigator Signed By: Alexandria L. Capuano -S Date Signed: 02-27-2026 16:27:44	DATE ISSUED 2/27/2026

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."