DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 oradevices2firmresponse@fda.hhs.gov	9/9/2024-9/12/2024
	FEI NUMBER 3010663372

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Craig P. Black, CEO and Owner

FIRM NAME	STREET ADDRESS
DeGen Medical Inc.	1321c N Cashua Dr
CITY, STATE, ZIP CODE, COUNTRY Florence, SC 29501-6939	TYPE ESTABLISHMENT INSPECTED Specification Developer/ Complaint File Unit

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 I OBSERVED:

OBSERVATION 1

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically, during the review of your Design Validation activities for the (b) (4), a Class II medical device, I observed in the (b) (4) Design Validation/ Verification Report, EDS-07112, Rev. 01, that identified user needs were not validated by the design validation activities performed. For example:

1. There is no empirical data that demonstrates the (b) (4) can restore (b) (4). There are no recorded measurements of the (b) (4) between the (b) (4) before and after the device installation.
2. There is not data or evidence the (b) (4) of the (b) (4) will permit x-ray techniques to (b) (4) and allow a physician to observe (b) (4) with (b) (4).
3. The mechanical requirement to support patient sizes that were not considered obese were not tested as part of design validation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Gamal A Norton, Investigator X Gamal A Norton Investigator Signed By: GAMAL A. NORTON - S Date Signed: 09-12-2024 12:13:30	9/12/2024

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OBSERVATION 2

The design was not validated under actual or simulated use conditions.

Specifically, your firm's design validation activities for the (b) (4), a Class II medical device was not performed under actual or an adequate simulated use condition. In the (b) (4) Design Validation/ Verification Report, EDS-07112, Rev. 1 the design validation case reported on page 25 used a model of (b) (4). This model does not provide an adequate environment to simulate a surgical procedure for installation of the (b) (4).

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gamal A Norton, Investigator

X Gamal A Norton
Investigator
Signed By: GAMAL A. NORTON - S
Date Signed: 09-12-2024 12:13:30

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Annotations to Observations

Observation 1: Annotation Intentionally Left Blank

Observation 2: Annotation Intentionally Left Blank

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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."