DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	9/16/2024-9/19/2024 FEI NUMBER 3015383864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jean-Charles Roussouly, Deputy CEO

FIRM NAME	STREET ADDRESS
S.M.A.I.O	Parc Technologique, 2 Place Berthe Morisot
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint-Priest, Metropole de Lyon, 69800 France	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 I OBSERVED:

OBSERVATION 1

Design plans that describe or reference the design and development activities and define responsibility for implementation have not been adequately established.

Specifically, your DDS-P-001_g procedure titled "Software Development Procedure" [effective date 07/12/2024] describes your medical device software design and development process; in addition to, the requirements needed to ensure compliance for the design control of your software. The following deficiencies were observed in the review of this procedure:

A. Page eight of the DDS-P-001_g procedure, under the definition section, defines Design Input as:

"Design Inputs: Inputs relating to product requirements are determined and records maintained. These inputs shall include:

a) functional, performance, usability and safety requirements, according to the intended use;
b) applicable regulatory requirements and standards;
c) applicable output(s) of risk management;
d) as appropriate, information derived from previous similar designs;
e) other requirements essential for design and development of the product and processes.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nadia R Barreda, Investigator	X Nadia R Barreda Investigator Signed By: 2003450420 Date Signed: 09-19-2024 04:55:19	9/19/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	9/16/2024-9/19/2024
	FEI NUMBER 3015383864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jean-Charles Roussouly, Deputy CEO	
FIRM NAME S.M.A.I.O	STREET ADDRESS Parc Technologique, 2 Place Berthe Morisot
CITY, STATE, ZIP CODE, COUNTRY Saint-Priest, Metropole de Lyon, 69800 France	TYPE ESTABLISHMENT INSPECTED Manufacturer

These inputs shall be reviewed for adequacy and approved
Source: ISO 13485:2016 section7.3.3"

This definition does not specify that the Design Inputs should be complete, unambiguous, or free of conflicting requirements.

B. Page 9 of the DDS-P-001_g procedure, under the definition section, states:

"Product Requirements Document (PRD) (DDS-F-025)- The document defines the requirements of the software, based on regulations, standards, risks associated with the device, business needs, user needs, including functional, performance, usability, and safety requirements. All outputs in the functional requirements section require both design verification and design validation. Design verification activities determine if the design output meets the design inputs and design validation activities determined if the design output meets the user needs. The final Product Requirements Document eliminate incomplete, ambiguous, or conflicting requirements. The supporting documentation is filled out for each requirement."

The PRD is described as a document that will be free of incomplete, ambiguous, or conflicting requirements. In the review of DDS-F-025-b, "Product Requirements Document" for the "KEOPS Balance Analyzer 3D, version 2.2", (b)(4) Design Inputs were observed to be either: ambiguous, incomplete, or lacking measurability. Further the outputs are not addressed in this document as stated in DDS-P-001_g.

C. Though your software validation for the "KEOPS BALANCE ANALYZER 3D, version 2.2" is complete, your risk analysis for the software is incomplete. During the review of your dFMEA (RMA-F-003) Cybersecurity Risk Analysis for the "KEOPS BALANCE ANALYZER 3D" version 2.2, (b)(4) risk hazards were documented as:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nadia R Barreda, Investigator	X Nadia R Barreda Investigator Signed By: 2003450420 Date Signed: 09-19-2024 04:56:19	DATE ISSUED 9/19/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	9/16/2024-9/19/2024 FEI NUMBER 3015383864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jean-Charles Roussouly, Deputy CEO	
FIRM NAME S.M.A.I.O	STREET ADDRESS Parc Technologique, 2 Place Berthe Morisot
CITY, STATE, ZIP CODE, COUNTRY Saint-Priest, Metropole de Lyon, 69800 France	TYPE ESTABLISHMENT INSPECTED Manufacturer

a. Under the column "Is the risk control measure implemented?", your firm documented "Partially" for the following reasons:
- the Cybersecurity procedure is in progress
- the Training matrix needs to be updated

or
- the Host vendor contract needs to be updated.

b. Under the column "Has the risk been reduced AFAP?", your firm documented "No"

As part of your design review process, the DDS-P-001_g procedure includes reviewing the dFMEA risk analysis for completeness, yet your firm approved and signed off the dFMEA for the "KEOPS BALANCE ANALYZER 3D, version 2.2" as complete.

Your Class II medical device, "KEOPS BALANCE ANALYZER 3D, version 2.2", is a stand-alone software used by orthopedic surgeons to view and measure x-ray images to plan surgical spine procedures. This software also includes tools for measuring anatomical components for the design specifications used to order surgical implants for patients. The software utilizes cloud services to store patients' data and imaging. Your firm also provides software technical support for your customers.

As a result of the deficiencies in procedure DDS-P-001_g, your design and development activities are not adequately established. Your firm has distributed a medical device software without a completed risk analysis.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nadia R Barreda, Investigator X Nadia R Barreda Investigator Signed By: 2003450420 Date Signed: 09-19-2024 04:55:19	9/19/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue Silver Spring, MD 20993 (301)594-4695 Fax:(301)594-4715	9/16/2024-9/19/2024 FEI NUMBER 3015383864

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jean-Charles Roussouly, Deputy CEO	
FIRM NAME S.M.A.I.O	STREET ADDRESS Parc Technologique, 2 Place Berthe Morisot
CITY, STATE, ZIP CODE, COUNTRY Saint-Priest, Metropole de Lyon, 69800 France	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nadia R Barreda, Investigator	X Nadia R Barreda Investigator Signed By: 2003450420 Date Signed: 09-19-2024 04:55:19	9/19/2024

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."