DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US FDA CDRH White Oak Building 66, Room 3540 10903 New Hampshire Ave. Silver Spring, MD 20993 301-796-5819 Industry Information: www.fda.gov/oc/industry	07/29 - 31/20204
	FEI NUMBER 3011575197

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Richard Donaca, CEO

FIRM NAME	STREET ADDRESS
Argon Medical Productions & Vertriebs Gesellschaft MBH & Co	Franz Kirstan Str. 1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bingen Am-Rhein, Germany D-55411	Device 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) (WE) OBSERVED:

1) Written MDR procedures have not been implemented. Specifically, the Argon Post Market Surveillance procedure A002 which includes procedures for adverse event notification does not describe criteria for Medical Device Reporting and does not provide details for how MDR reporting will be made.

2) An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have contributed to a serious injury. Specifically, the following complaints described that the dental implant failed to osseointegrate:

Complaint number, 23.058 received on April 23, 2023, implant 40065K3Pro.R/Short s/n [redacted]
implant 45065K3Pro.R/Short s/n [redacted]
Complaint number, 23.060 received on April 17, 2023, implant 40011K3Pro.R s/n [redacted]
Complaint number, 23.062 received on April 19, 2023, implant 40075K3Pro.R s/n [redacted]

Failure to osseointegrate results in additional dental procedure to remove the failed implant and install another implant.

ode

3) Labels of K3Pro Kronus Dental implants such as article 4009K3PRO.R do not bear a unique device identifier that meet the requirements of 801 Subpart B and 21 CFR830. Also, labeling for K3PROXP Line article ~~BSP.XP~~ 35020/3 do not include a unique device identifier and the code that retrieves from the labeled QR code cannot be found in the GUDID database.

BPS.XP

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Eich, Investigator	07/31/2024

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4) Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary. Specifically, complaints of failure of dental implants to osseointegrate are not investigated, for example Complaint number 23.058.

Annotation

1.) Promise to correct

2.) Promise to Corrected

3.) Promise to Correct

4.) Promise to Correct

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	SED	Stephen D. Eich, Investigator	07/31/2024