DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	3/11/2026-3/12/2026
	FEI NUMBER 2182799

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David G. Aamodt, President

FIRM NAME	STREET ADDRESS
Production Systems, Inc	4620 Chatsworth St N
CITY, STATE, ZIP CODE, COUNTRY Shoreview, MN 55126-5830	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 I OBSERVED:

OBSERVATION 1

One or more processes for risk management in product realization have not been documented.

Specifically,

Your firm manufacturer's cables and adaptors for electrosurgical cutting and coagulation devices and you failed to maintain risk management documentation. The following was not documented:

a. Risk management plan containing the details of the risk management activities conducted throughout the product lifecycle including information on when these activities occur and who is responsible for them. There was no documentation identifying the criteria for risk acceptability and the method to determine probability of occurrence and severity of harm.

b. Hazard identification records documenting potential hazards associated with the device and the manufacturing process under normal and reasonably foreseeable misuse conditions. There was no documentation identifying risk estimation metrics showing severity and probability ratings for each identified hazard.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Alicia U Jacobo, Investigator X Alicia U Jacobo Investigator Signed By: Alicia U. Jacobo -S Date Signed: 03-12-2026 13:32:39	3/12/2026

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c. Risk evaluation records demonstrating how identified risks were evaluated against pre-established acceptance criteria.

d. Risk control measures to reduce risk to acceptable levels. There was no verification and validation records confirming the implementation and effectiveness of risk control measures.

e. Residual risk justifications, including benefit-risk analyses supporting the acceptance of residual risks.

f. Risk management reports to demonstrate that the risk management plan has been appropriately implemented, the overall residual risk is acceptable, and that appropriate processes are in place to collect and review post-production data.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alicia U Jacobo, Investigator	X Alicia U Jacobo Investigator Signed By: Alicia U. Jacobo -S Date Signed: 03-12-2026 13:32:39	DATE ISSUED 3/12/2026

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Alicia U Jacobo, Investigator	X Alicia U Jacobo Investigator Signed By: Alicia U. Jacobo -S Date Signed: 03-12-2026 13:32:39	DATE ISSUED 3/12/2026

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."