DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	2/3/2026-2/5/2026
	FEI NUMBER 1720734

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jeffrey V. Baldwin, Chief Executive Officer (CEO)	
FIRM NAME	**STREET ADDRESS**
IPAX, Incorporated	2700 S Raritan St
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Englewood, CO 80110-1102	Contract 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 adequately documented.

Specifically,

a) Your company's "Work Instructions for LifeCell Revolve Assemblies", Doc: QSWI 3.007, Dated: 12/2/2024, Rev 010 describes the production process your company performs to manufacture an adipose collection system for autologous grafting. The document also includes a device "(b) (4)" in Section 12.8.1, which involves a functional test of the (b) (4) assembly. Note that your company's Director of Operations stated that the (b) (4) assembly serves as an essential function of the device to strain out the patient's serum from the adipose tissue collected for subsequent autologous implantation. I then asked your company's CEO and Director of Operations to identify where your company documented the risk associated with the handle (b) (4) functional test in production. However, your company's CEO and Director of Operations responded that they could not locate a corresponding risk following their review of the "LifeCell (pFMEA 001)", Doc: pFMEA 001, Dated: 07/06/2020, Rev.: 002, nor any other risk documentation.

b) During my review of your company's "LifeCell (pFMEA 001)", Doc: pFMEA 001, Dated:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Matthew M Vernon, Investigator	X Matthew M Vernon Investigator Signed By: 2001860154 Date Signed: 02-05-2026 17:01:33	2/5/2026

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jeffrey V. Baldwin, Chief Executive Officer (CEO)	
FIRM NAME IPAX, Incorporated	STREET ADDRESS 2700 S Raritan St
CITY, STATE, ZIP CODE, COUNTRY Englewood, CO 80110-1102	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer

07/06/2020, Rev.: 002, I noted that the document's "Possible Hazards" table lists "loss of vacuum" as a severity of "serious"/ "Severity* Factor Ranking" of "(b)(4)" for the adipose collection system for autologous grafting device. To the contrary, I noted that the risks identified in rows BFE-016, BFE-019, BFE-031 have the same "Potential Hazard" of "vacuum loss" but with a corresponding "severity" factor ranking of "(b)(4)"/"minor". Your company's CEO responded by clarifying that the "severity" factor ranking of "(b)(4)"/"minor" corresponds to the "Procedural Delay" in the pFMEA's "Potential Failure Effect" column that has a "severity" factor ranking of "(b)(4)"/"minor" in the document's "Possible Hazards" table. Your company's CEO then acknowledged the lack of clarity related to the traceability of the "Possible Hazards" table to the hazards and corresponding severities presented in the pFMEA's risks/rows.

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Annotations to Observations

Observation 1: Promised to correct

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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."