PIPAC ESSENTIALS

# Regulatory Background (U.S.)

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# Disclosures

- I do not have any relevant financial relationships with any ineligible companies.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

# Medical Device Definition

- Instrument, apparatus, machine, implant, in vitro reagent, including component, port or accessory
- Diagnoses, cures, mitigates, treats, or prevent disease or condition
- Affects structure or function of body
- Doesn’t achieve purpose as a drug
- Excludes certain software functions such as data storage, administrative support, electronic patient records

Source: Section 201(h) of the Food, Drug, and Cosmetic Act

# Combination Products

- Combination Products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.
- Involves at least two regulatory components types:
  - Drug + Device
  - Biologic + Device
  - Drug + Biologic
  - Drug + Device + Biologic

Source: https://www.fda.gov/combination-products/about-combination-products

# IND or IDE

- IND or IDE
- The submission type is determined based on the primary mode of action (PMOA) of the combination.
- Depending on the PMOA, the FDA determine whether the submission will be reviewed by the drugs, biologics or device division.

Source: https://www.fda.gov/combination-products/about-combination-products

# Regulatory Pathway at COH

- Goal: To test the safety and feasibility of PIPAC in a US patient population with limited treatment options.
- The study proposed was a combination study using commercially available drugs and an investigational device.
- Drug route of administration and delivery device are considered investigational.
  - The proposed delivery mechanism for the drugs was not in accordance with the US approval.
  - The device was not approved in the US.

# Regulatory Pathway at COH

- Next step was to determine the PMOA.
- The intended use of drugs described in the study is to treat a disease.
- Intended use for the device in the study was delivery mechanism.
- Therefore, the drugs are the PMOA.
- Conclusion, the regulatory submission type was an IND.
- FDA's lead review is conducted by the Center for Drug Evaluation and Research (CDER) with a consult to the Center of Devices and Radiological Health (CDRH).

# Regulatory Pathway at COH

- The regulatory submission (IND) contained detailed information about the drugs and the device.
- FDA granted a Study May Proceed Letter.
- Current studies under the active IND:
  - NCT04329494 - Safety and Efficacy of PIPAC in ovarian, uterine, appendiceal, colorectal and gastric cancer patients with peritoneal carcinomatosis (PC)
    - Status: Open to Accrual
  - NCT05285358 – Safety of PIPAC in biliary tract cancer patients with peritoneal metastases
    - Status: Open to Accrual

# Investigational Device

- Nebulizer
- Manufacturer: Reger Medizintechnik Gmbh
- CE Certified (Class IIA)
- FDA Device classification: Class II

# US Device Regulations Class II

- Class II devices (moderate to high risk): general and special controls.
  - General Controls (adulterated, misbranded, establishment registration / device listing, 510k, banned devices, notifications, records/reports on devices).
  - Special Controls (performance standards, post market surveillance, patient registries, special labeling requirements, premarket data requirements and guidelines.

# New Version

- QuattroJet – Item code: 770-14
- Per the Reger's brochure, the QuattroJet is designed for best spray performance.
- Indication: It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.

# QuattroJet – Regulatory Pathway

New Search | Back To Search Results

| | |
|---|---|
| **Device Classification Name** | laparoscope, general & plastic surgery |
| **510(k) Number** | K231622 |
| **Device Name** | REGER Nebulizer Irrigation Cannula |
| **Applicant** | REGER Medizintechnik, GmbH<br>Gewerbestrasse 10<br>Villingendorf, DE 78667 |
| **Applicant Contact** | Christopher Kohn |
| **Correspondent** | QSR Consulting<br>10807 Dakota Ranch Rd.<br>Santee, CA 92071 |
| **Correspondent Contact** | Kenneth Kleinhenz |
| **Regulation Number** | 876.1500 |
| **Classification Product Code** | GCJ |
| **Date Received** | 06/02/2023 |
| **Decision Date** | 09/29/2023 |
| **Decision** | Substantially Equivalent (SESE) |
| **Regulation Medical Specialty** | Gastroenterology/Urology |
| **510k Review Panel** | General & Plastic Surgery |
| **Summary** | Summary |
| **Type** | Traditional |
| **Reviewed by Third Party** | No |
| **Combination Product** | No |

Source: U.S Food & Drug Administration

# Key Takeaways

- To avoid submission delays, is important to complete a thorough regulatory review.
- Use FDA resources to determine the correct regulatory submission.
- The Office of Combination Products at the FDA is available to assist with the study classification.
- Open line of communication with the device manufacturers.

# Questions