PeDIA, LLC
% Christina Henza
Regulatory
Ultra LifeScience Solutions Inc.
872 S. Milwaukee Avenue, #286
Libertyville, Illinois 60048

Re: K181424
Trade/Device Name: Pediatric Device for Induction of Anesthesia (PeDIA)
Regulation Number: 21 CFR 868.5320
Regulation Name: Reservoir Bag
Regulatory Class: Class I
Product Code: BTC
Dated: August 29, 2018
Received: August 29, 2018

Dear Christina Henza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181424

Device Name
Pediatric Device for Induction of Anesthesia (PeDIA)

Indications for Use *(Describe)*
The pediatric device for induction of anesthesia (PeDIA) is an alternative to a face mask for the inhalation induction of anesthesia, and is intended for the delivery of nitrous and/or anesthetic gases to children age three years and older. It is intended to be used prior to IV insertion, LMA/endotracheal intubation, and/or conversion to a standard mask induction

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5 510 (K) SUMMARY FOR PEDIA

Date: 9/21/2018

I. SUBMITTTER/ 510(K) HOLDER

PeDIA, LLC
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Submission Contact:

Christina Henza
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II. DEVICE NAME

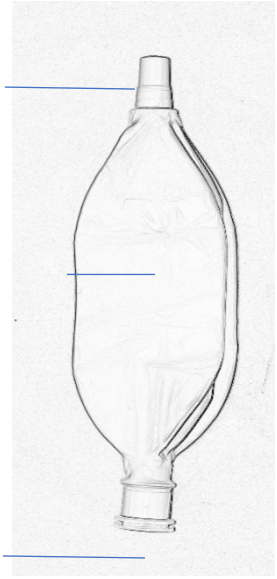
Proprietary Name: Pediatric Device for Induction of Anesthesia (PeDIA)
Common/Usual Name: Reservoir bag
Classification Name: Bag
Device Class: I
Panel: Anesthesiology
Product Code: BTC
Regulation: 868.5320

III. PREDICATE DEVICES

PeDIA is substantially equivalent to the existing class I King Breathing Bags (predicate device - K880680) by King Systems. The proposed PeDIA device is submitted for premarket notification [510(k) pathway] because the addition of the extra connector/mouthpiece causes the device to exceed the limitations to the exemption in 21 CFR 868.9(b) in that it introduces a different scientific technology to a reservoir bag.

IV. DEVICE DESCRIPTION

The Pediatric Device for Induction of Anesthesia (PeDIA) is a single-use, disposable, mask-free anesthetic delivery system and method used for children 3 years and older.



Mouthpiece (whistle) used by patient to inhale and exhale gases

Balloon fills with anesthetic gases

Universal connector attaches to anesthesia breathing circuit

The balloon is a standard, legally marketed reservoir bag that is modified by the addition of a whistle at the opposite end of the connector (which is a closed end on standard balloons). This balloon is used in place of the mask for the initial application of anesthesia gasses. Once the child is sedated the product is removed and replaced with a standard pediatric mask for the duration of anesthesia.

Compatible Devices

The proposed PeDIA device is compatible with standard anesthesia circuits, attaching in place of the mask.

V. INDICATIONS FOR USE

The pediatric device for induction of anesthesia (PeDIA) is an alternative to a face mask for the inhalation induction of anesthesia, and is intended for the delivery of nitrous and/or anesthetic gases to children age three years and older. It is intended to be used prior to IV insertion, LMA/endotracheal intubation, and/or conversion to a standard mask induction.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF PROPOSED COMPARED TO THE PREDICATE DEVICE

Substantial Equivalence Table				
		Proposed Device	**Predicate Device**	**Explanation of Variation**
Regulatory Information	Name	PeDIA	King Systems breathing bag	N/A
	510(k)#	K181424	K880680	The proposed device exceeds the limitations to the exemption in 21 CFR 868.9(b)
	Predicate	King Systems Breathing Bag	unknown	Equivalent.
	Product Code	BTC	BTC	Same
	Class	1	1	Same
	Combination Product	No	No	Same
	Regulation Number	868.5320	868.5320	Same
	Regulation Generic Name	Breathing bag	Breathing bag	Same
Intended use	Regulation Intended Use	for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient's ventilation.	for use in a breathing circuit as a reservoir for breathing gas and to assist, control, or monitor a patient's ventilation.	Same
	Indications	The pediatric device for induction of anesthesia (PeDIA) is an alternative to a face mask for the inhalation induction of anesthesia, and is intended for the delivery of nitrous and/or anesthetic gases to children age three years and older. It is intended to be used prior to IV insertion, LMA/endotracheal intubation, and/or conversion to a standard mask induction.	Predicate device Intended Use is not included within the labeling, which implies it is consistent with the regulation intended use.	Equivalent. The PeDIA device falls within the regulation intended use and the predicate intended use.
	Pediatric Use	Exclusively pediatric	Pediatric and adult versions available	Equivalent.
Technological Characteristics	Materials	Neoprene (bag) TPO (bushing) PVC Adhesive ABS	Neoprene (bag) TPO (bushing) PVC	Equivalent.
	Biocompatibility	Biocompatible	Biocompatible	Same.

Substantial Equivalence Table				
		Proposed Device	**Predicate Device**	**Explanation of Variation**
	Anatomical sites	Mouth, indirect contact through gas inhalation to airway tissues.	indirect contact through gas inhalation to airway tissues	Equivalent.
	Contact Type	External communicating device - tissues, indirect	External communicating device -tissues, indirect	Same.
	Contact duration	Limited ≤ 24 hours	Limited ≤ 24 hours	Same.
	Components	Breathing Bag Connector Tape Adhesive whistle	Breathing bag Connector Tape	Equivalent.
	Performance	ISO 5362 & ISO 5356-1	ISO 5362 & ISO 5356-1	Equivalent
	Sterile?	Not sterile	Not sterile	Same
	Storage conditions	keep dry	Keep dry	Same
	Shelf Life	Not restricted	Not restricted	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Shelf-Life testing:

The device is non-sterile and there is no restriction on shelf-life

Biocompatibility testing:

The biocompatibility evaluation for the PeDIA device was conducted in accordance with the FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (Attachment A)* published June 16, 2016 *This device is categorized in ISO 10993-1:2009 as "External communicating device - tissue/bone/dentin" per section 5.2.2(b). The device will have limited contact of less than or equal to 24 hours.* Testing completed on this device includes:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Toxicity
- Pyrogenicity

Risk Based Approach

The Risk Management report was prepared to determine the necessary risk-mitigation measures in the design and the manufacturing of the PeDIA device. Many of the risks are mitigated by design, labels, and biocompatibility, the associated information is included in the referenced sections. Mechanical and performance testing is included in this section. The risks related to all applicable hazards which were identified for the PeDIA device have been reduced to the acceptable level by mitigation. Therefore, all residual risks post-mitigation have been deemed acceptable for this design.

Standard Compliance

Standard compliance to ISO 5362 Anesthetic Reservoir bags and ISO 5356-1, Anesthetic and respiratory equipment – conical connectors – Part 1: Cones and Sockets was confirmed by a MET Laboratories. The standard includes requirements for connectivity to adjacent anesthetic equipment, capacity, leakage, disconnection, resistance to pressure, and design requirements.

Verification

Verification testing to confirm all requirements other than those addressed by the standardized testing is completed per a preapproved protocol and includes confirmation of specification, labeling, and instructional requirements.

Conclusion

Tests were successfully performed and all acceptance criteria were met, thus confirming that the PeDIA device satisfactorily meets requirements. There were no different questions of safety and effectiveness identified during review of Risk Management documentation or execution of Validation activities.

VIII. CONCLUSIONS

Based on the information and supporting documentation provided in the premarket notification, the PeDIA device is substantially equivalent to the cited predicate device. Testing demonstrates that the PeDIA device fulfills prospectively defined design and performance specifications.