DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 11, 2016

ExploraMed NC7, Inc.
Keri Y. Ng
VP Regulatory, Quality, Clinical
201 San Antonio Circle #172
Mountain View, CA 94040

Re: K161266
Trade/Device Name: Athena Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: June 29, 2016
Received: June 30, 2016

Dear Keri Y. Ng:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Douglas Silverstein -S
2016.08.11 14:22:47 -04'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161266

Device Name
Athena Breast Pump

Indications for Use *(Describe)*
The ExploraMed NC7 Athena Breast Pump is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.

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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510(K) Summary – K161266 Athena Breast Pump

Sponsor/Submitter:	ExploraMed NC7, Inc 201 San Antonio Circle #172 Mountain View, CA 94040
Contact Person:	John Chang Vice President, R&D Phone: (650) 559-5805 Fax: (650) 284-2552
Date Prepared:	August 11, 2016
Device Trade Name:	Athena Breast Pump
Common Name:	Breast Pump
Device Classification:	Class II
Regulation Number:	21 CFR 884.5160
Classification Name:	Pump, Breast, Powered
Product Code:	HGX
Predicate Device:	Medela Ag Freestyle Breast Pump (K150499)
Device Description:	The ExploraMed NC7 Athena Breast Pump (Athena) is a small electric breast pump that is intended for lactating women to express and collect breast milk. The subject device is intended for multiple uses with a single user. Athena may be operated as a single or double pumping system. For a user to pump both breasts simultaneously, she would need to use two (2) Athena devices at the same time, one on each breast. Athena mainly consists of five components: Pump, Flange, Flextube, Milk Bag, and Charger. The Flange and Flextube are reusable components that may be manually cleaned. The Milk Bag is disposable and intended for single use. Athena is a battery-powered electro-mechanical device that contains software. It is comprised of materials commonly found in medical devices such as polypropylene and silicone. All milk-contacting components are constructed out of food-grade materials that are compliant with 21 CFR 174-179. None of the milk-pathway components are made out of natural or synthetic rubber. Athena is considered a skin-contacting device with a limited (≤24 hours) contact duration.

Device Operation:	The user turns on the Pump by pressing the "On/Off" button and aligns the nipple in the Flange. Following alignment, the user starts the pumping session by pressing the "Play/Pause" button on the control panel of the Pump. The subject device has two modes: Stimulation and Expression. The Pump starts pumping in Stimulation mode at a moderate vacuum level to stimulate milk letdown from the user. After letdown, the Pump changes to Expression mode and increases the vacuum level. The user is able to increase or decrease the vacuum level. When the pumping session ends, the user removes the Pump from the breast; separates the Flange from the Pump; and removes the Milk Bag. The Charger can be inserted into the power port to charge the Pump when not in use.
Indications for Use:	The ExploraMed NC7 Athena Breast Pump is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user.
Technological Characteristics:	Athena generates suction and extracts breast milk. The Flange fits on the breast to create a seal and facilitate the suction. The Pump has two modes and has user-adjustable suction levels ranging from 60mmHg to 245mmHg.

Substantial Equivalence Comparison

Attribute	**Predicate Device** **Medela Ag Freestyle Breast Pump**	**Subject Device** **ExploraMed NC7 Athena Breast Pump**
510(k) number	K150499	K161266
Intended Use	Express milk from breast	Same, Express milk from breast
Single User	Yes	Same, Yes
Provided Non-Sterile	Yes	Same, Yes
Re-usable	Yes	Same, Yes
Direct User Contact	Yes	Same, Yes
Technological Characteristics	Electrical pressure control pumping system to generate suction	Same, Electrical pressure control pumping system to generate suction
Power Source	AC Adaptor or Li-Ion Battery	Same, Li-Ion Battery
Suction Levels (mmHg)	40-245	Same, 60-245
Adjustable Suction Levels	Yes	Same, Yes
Suction Settings	9	7
Back Flow Protection	Yes	Same, Yes
Control Mechanism	Microcontroller	Same, Microcontroller
Single or Double Pumping	Single or Double	Same, Single or Double
Mobile	Yes	Same, Yes
Number of Reusable Components That Require Cleaning	5	2

The physical characteristics of Athena are similar to the predicate device as demonstrated by the following:

- Athena is intended to generate suction to express milk from a lactating mother, which is identical to the predicate device.
- Athena is reusable and provided non-sterile to the customer, which is the same as the predicate device.
- The operating suction levels and suction cycles for Athena are within the established range for the predicate device.
- Both devices utilize a closed pumping system.
- Both devices use an electrical pressure control pumping system to generate suction.
- Athena has adjustable suction levels and a backflow protection mechanism, identical to the predicate device.
- Both the predicate device and subject device are intended to be portable.

The differences between the subject device and the predicate device are as follows:

- There are seven (7) vacuum levels in Athena and nine (9) vacuum levels in the predicate device.
- Athena automatically switches from Stimulation mode to Expression mode. It does not allow the user to manually alternate between modes. The predicate device has a let-down button that allows the user to manually change phases.
- Athena is operative via Li Ion battery and the predicate consists of Li Ion battery and AC adaptor.
- There are only two components that require manual cleaning in Athena; whereas, there are five components that require manual cleaning in the predicate.

The differences between the subject device and predicate device do not raise different questions of safety or efficacy.

Performance Data: The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Bench Testing
  - Reliability testing
  - Vacuum Profile testing
  - Sound testing
  - Cycle Frequency testing
  - Dimensional testing
  - Bag Pressure testing
  - Bag Puncture Verification testing
- Electrical Safety
  - IEC 60601-1+A1: 2012
  - IEC 60601-1-11:2015
  - IEC 60601-1-6: 2010 + A1:2013
  - IEC 62366:2007 + A1: 2014
  - IEC 62133:2012
- Electromagnetic Compatibility
  - IEC 60601-1-2:2014
- Biocompatibility (ISO 10993-1)
  - Sensitization
  - Irritation
  - Cytotoxicity

- Cleaning Validation
  - AAMI TIR 12:2010
  - AAMI TIR 30:2011
  - FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17, 2015 (UCM253010).
- Software Validation
  - FDA Guidance: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

Clinical Data: Clinical testing was not required to demonstrate substantial equivalence of the Athena to its predicate device.

Animal Data: No animal performance data was required to demonstrate substantial equivalence of the Athena to its predicate device.

Summary of Substantial Equivalence: The ExploraMed NC7 Athena Breast Pump is substantially equivalent to the predicate device as confirmed through relevant performance tests and device attributes. Therefore, the ExploraMed NC7 Athena Breast Pump is as safe and effective as the predicate device.