May 19, 2022

Artiglass Srl
Sabrina Baccarin
Quality Director
Via Piemonte 13
Due Carrare, Padova 35020
Italy

Re: K213800
Trade/Device Name: Artiglass NRFitTM Tip L.O.R. Glass Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QEH
Dated: April 15, 2022
Received: April 21, 2022

Dear Sabrina Baccarin:

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 and Part 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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, Sub part 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213800

Device Name
Artiglass NRFit Tip L.O.R. Glass Syringes

Indications for Use *(Describe)*
The Artiglass NRFit tip Glass Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard textbooks. These syringes are not intended for injection or aspiration.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5
510 (K) Summary

Applicant: Artiglass Srl
via Piemonte 13, Due Carrare Padova. Italy

Contact Person: Sabrina Baccarin
Contact Title: Quality Director
Contact Phone Number: +39 049 5290442
Contact Fax Number: +39 049 5290446
E-mail: regulatory@artiglass.it

Official Correspondent: same as Contact Person

Date Summary Prepared: April 15, 2022

Classification: 21 CFR § 880.5860, Class II
Classification name: Piston Syringe
Product Code: QEH
Trade Names : Artiglass NRFit™ Tip L.O.R. Glass Syringes
Generic/Common Name: NRFitTM Tip L.O.R. Glass Syringes

Predicate device
Predicate Device: Artiglass L.O.R. Glass Syringes
510(k) Number: K122416
510(k) Clearance Date: May 3, 2013
Regulation Number: 21 CFR § 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF

Indications for use
The Artiglass NRFit TM tip Glass Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard textbooks. These syringes are not intended for injection or aspiration.

Intended population
The syringe is intended for adult patient.

Product Description
The Artiglass NRFit TM tip Glass Syringe reusable syringes provided not sterile with ISO 80369-6 (NRFit™) compliant fittings. They are available in 5mL and 10mL, lock and slip configurations and 5mL and 10mL lock configurations. The NRFit™ tips allow for connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices. The syringe assembly consists of a borosilicate neutral glass barrel with a graduated scale in milliliters (mL), a borosilicate neutral glass plunger and a nickel-plated brass tip. The plunger rod is amber colored to designate a device intended to only connect to ISO 80369-6 compatible devices such as spinal or epidural needles.

Comparison of Technological Characteristics
The comparison table of technological characteristics is documented in the following table Predicate Device Comparison.

TABLE: Predicate Device Comparison

Model	**Special 510(k) Artiglass NRFitTM Tip L.O.R. Glass Syringes Subject Device**	**510(k) Artiglass L.O.R. Glass Syringes K122416**
Product Code	QEH	FMF (1)
Common Name	Syringe, Piston	Same
Regulation Number	880.5860	Same
Regulation Description	Piston Syringe	Same
Submission Type	510(k) Special	510(k) Traditional
510(k) Number	NA	K122416
Intended Use	The Artiglass NRFit ™ tip Glass Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard textbooks. These syringes are not intended for injection or aspiration. The syringe is intended for adult patient.	Same
Reusable/Sigle use	Single use (7)	Reusable
Sterility	Provided not sterile The non-sterile NRFit ™ syringe is intended to be sterilized prior to use to repackagers/medical device manufacturers.	Same
Tip	NRFit ™ Connector, Luer Metal and Luer Lock	Luer Glass, Luer Metal and Luer Lock (2)
Tip material	Nickel plated brass	Same
Syringe Barrel	Borosilicate neutral glass	Same
Plunger	Borosilicate neutral glass	Same
Available Volumes	5 mL, 10 mL	Same

Model	**Special 510(k) Artiglass NRFitTM Tip L.O.R. Glass Syringes Subject Device**	**510(k) Artiglass L.O.R. Glass Syringes K122416**
Calibrated Barrel Volume	yes	Same
Recommended sterilization method	Steam	Same
NRFit Connector	Yes; compliant with ISO 80369-6	No; (2)
Package	Individually, in bulk	Same
Biocompatibility Compliance	ISO 10993-1 Fifth edition 2018-08	ISO 10993-1 Fourth edition 2009-10-15 (3)
	10993-4 Third edition 2017-04	ISO 10993-4:2002/amd 1:2006 Hemocompatibility (Interaction with blood) (4)
	same	ISO 10993-5:2009
	same	ISO 10993-10:2010 Irritation and skin sensitization
	10993-11 Third edition 2017-09	ISO 10993-11:2006 Systemic toxicity (5)
Standard Compliance	ISO 595-1:1988, ISO 595-2:1987, ISO 80369-6:2016, ISO 80369-20:2015	ISO 594-1:1986, ISO 594-2:1998, ISO 595-1:1988, ISO 595-2:1987 (6)

Discussions of differences in technological characteristics

(1) The Product code is different. The differences were addressed through ISO 80369-6 and ISO 80369-20 and performance testing.
(2) The tip of the subject device is specific. The differences were addressed through ISO 80369-6 and ISO 80369-20 performance testing.
(3) The differences were addressed through the "Artiglass NRFitTM Tip L.O.R. Glass Syringes Biological evaluation plan"
(4) The tests have been repeated according to 10993-4 Third edition 2017-04 and ASTM F756-17 (Hemolysis)
(5) The tests have been repeated according to 10993-11 Third edition 2017-09
(6) The differences were addressed through ISO 80369-6, ISO 80369-20 and ISO 7886-1 performance testing.
(7) The syringe is intended for a single use. This not affect the effectiveness and safety of the device itself.

Performance Testing in Support of Substantial Equivalence Determination

The performance of the subject Artiglass NRFitTM Tip L.O.R. Glass Syringes is demonstrated as tested per the applicable requirements of ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications -Part 6: Connectors for neuraxial applications.

Non-Clinical Tests:

1. Leakage by pressure decay per ISO 80369-6
2. Sub-atmospheric-pressure air leakage per ISO 80369-6
3. Resistance to separation from axial load per ISO 80369-6
4. Resistance to separation from unscrewing per ISO 80369-6
5. Resistance to overriding per ISO 80369-6
6. Leakage between piston and barrel per ISO 595-2
7. Ink adhesion (permanence of marking) per ISO 595-2
8. Identification of burrs, hooks, cracks, foreign contamination, missing components per visual inspection
9. Fluid leakage requirement per ISO 80369-6
10. Stress Cracking per ISO 80369-6

Connector testing performed on the proposed device included the items listed below, in accordance with ISO 80369-6:2016, using the test methods provided in ISO 80369-20. The testing demonstrates the proposed devices conform to the applicable requirements of ISO 80369-6:2016

Individual test Defined in ISO 80369-6	**Requirement Defined in ISO 80369-6**	**Test Method Defined in ISO 80369-20**
Fluid leakage requirement	Clause 6.1.1	Annex B
Leakage by pressure decay	Clause 6.1.2	Annex B
Sub-atmospheric-pressure air leakage	Clause 6.2	Annex D
Stress Cracking	Clause 6.3	Annex E
Resistance to separation from axial load	Clause 6.4	Annex F
Resistance to separation from unscrewing	Clause 6.5	Annex G
Resistance to overriding	Clause 6.6	Annex H

Even though the geometry of the tip is slightly different in the subject device manufactured by Artiglass, the results of the biocompatibility testing performed by Artiglass on the previously cleared syringe can be considered adequate also to assess the biocompatibility of the subject device.
The materials of the components of the test article are identical to the materials of the correspondent components of the subject medical device in its final finished form in formulation, processing, and no other chemicals have been added. No changes in material have occurred since the biocompatibility testing performed by the manufacturer on the predicate device Artiglass L.O.R. Glass Syringe. The change in the tip shape does not pose new issues of biocompatibility as the test article represents a worst case in respect to the subject device.

Clinical and Animal Tests:
Clinical tests were not required to demonstrate performance of between the subject and predicate devices. Product functionality has been adequately assessed by nonclinical tests.

Conclusion:
The submitted and the predicate device have the same indications for use and technological characteristics. The test results and comparison results show that the proposed device is substantially equivalent to the predicate devices in performance, materials, intended use, technological and operational characteristics.

Based on the intended use, technological characteristics, and performance testing, the proposed Artiglass NRFitTM Tip L.O.R. Glass Syringes has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.