September 3, 2019

TOP Corporation
℅ Jonathan Gilbert
Regulatory Affairs Consultant to TOP/MHC
Jon Gilbert
1641 Jeurissen Lane
Chanhassen, Minnesota 55317

Re: K182765
Trade/Device Name: TOP Corporation NRFit™ Tip Glass Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QEH
Dated: July 30, 2019
Received: July 31, 2019

Dear Jonathan Gilbert:

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/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, 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 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,

For Alan Stevens
Assistant Director
Team Health Technology 3 – Injection Devices
Division of Health Technology 3
Office of Health Technology 3
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182765

Device Name

TOP Corporation NRFit™ Tip Glass Syringes

Indications for Use *(Describe)*

The Top NRFit Lock Tip and Slip Tip LOR Syringes and the Additive Slip Tip Syringe are intended to be used with the ISO 80369-6 NRFit neuraxial compliant epidural needles for locating the epidural space, for local administration, and regional administration excluding subarachnoid/spinal block.

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.

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510(k) Summary – K182765

Submitter Sponsor: TOP Corporation
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Contact: Jon Gilbert, Consultant
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Date of Preparation: September 24, 2018

Subject Device:

Common Name:	Neuraxial Tip Syringes
Trade Name:	TOP Corporation NRFit™ Tip Glass Syringes
Regulation Number:	21 CFR880.5860
Regulation Name:	Piston syringe
Review Panel:	General Hospital
Regulatory Class:	Class II
Product Code:	QEH
Primary Predicate:	Vesco Medical NRFit Tip
Syringe 510(k):	K170218 cleared Feb 24, 2017

Device Description:

The TOP NRFit™ Tip Syringes are provided sterile. They are single use devices consisting of rigid USP 2 glass plungers and glass barrels with metal slip tips designed as the ISO 80369 - 6 compliant neuraxial connector which allows for connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices. The syringe barrels are printed with graduated markings in cc (milliliters) indicating the volume of liquid inside the syringe barrel. The proposed models for the neuraxial devices are listed below in Table 1 and 1a, where Table 1a part numbers identify products which include a distributor logo on the syringe barrel.

Table 1. TOP Corporation Models and Description	
TDR-621-01	5cc Neuraxial Slip Tip Glass Syringe
TDR-621-02	5cc Neuraxial Lock Tip Glass Syringe
TDR-620-11	5cc Neuraxial Additive Slip Tip Glass Syringe
TDR-621-21	10cc Neuraxial Slip Tip Glass Syringe
TDR-621-22	10cc Neuraxial Lock Tip Glass Syringe

Table 1a. Part Numbers and Descriptions for syringes with logo	
TDR-134-01	5cc Neuraxial Slip Tip Glass Syringe (w/ logo)
TDR-134-02	5cc Neuraxial Lock Tip Glass Syringe (w/ logo)
TDR-133-01	5cc Neuraxial Additive Slip Tip Glass Syringe (w/ logo)
TDR-621-31	10cc Neuraxial Slip Tip Glass Syringe (w/ logo)
TDR-621-32	10cc Neuraxial Lock Tip Glass Syringe (w/ logo)

Indications for Use:

The Top NRFit Lock Tip and Slip Tip LOR Syringes and the Additive Slip Tip Syringe are intended to be used with the ISO 80369-6 NRFit neuraxial compliant epidural needles for locating the epidural space, for local administration, and regional administration excluding subarachnoid/spinal block.

Discussion of differences in Indications for Use

The subject device indications are a subset of indications within the broader indications recently cleared in predicate K170218, and as such are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and, do not affect the safety and effectiveness when used as labeled.

Technological Characteristics:

Table 2. Technological Characteristics & Substantial Equivalence

Device	Vesco Medical K170218 Primary Predicate	TOP K843414 Secondary Predicate	TOP CORPORATION Neuraxial* K182765 Subject Device	Comparison
Syringe Barrel:	Polypropylene	USP 2 borosilicate glass	USP 1 borosilicate glass	Same as K843414, Different materials K170218
Plunger Tip:	Synthetic Rubber	Synthetic Rubber	Synthetic Rubber	Same as K843414 & K170218
Plunger:	Polypropylene	USP 2 borosilicate glass	USP 1 borosilicate glass, or Polypropylene	Same as K843414, Different materials K170218
Syringe Piston Lube Coating:	Polydimethylsiloxane, Silanol Terminated	Medical Grade Oil	Medical Grade Oil	Same as K843414, Different materials

				K170218
Syringe sizes:	3-20mL	1-100mL	5mL and 10mL	Different sizes K170218
Connection:	NRFit™	Luer lock, Luer Slip	NRFit™	Same K170218, Different connection K843414
Calibrated Barrel Volume:	Yes	Yes	Yes	Same as K843414 & K170218
Recommended Sterilization method:	EtO	EtO	EtO	Same as K843414 & K170218

Discussion of differences in technological characteristics

Differences in materials between the subject device K182765 and primary predicate K170218 were addressed through biocompatibility testing per ISO 10993-1 Biological evaluation of medical devices.

Differences in syringe sizes and neuraxial tip between the subject device K182765 and K843414 were addressed through ISO 80369-6, ISO 80369-20 and ISO 7886-1 performance testing.

These differences do not raise different questions of safety and effectiveness.

The clinical technique, technical specifications, materials used, and sterility status (validation and sterility assurance level) are substantially equivalent to either K843414 or K170218. As stated above, the NRFit™ tip syringes provide connections of neuraxial specific applications while reducing the likelihood of misconnections to non-neuraxial devices.

Performance Testing:

The performance of the subject TOP NRFit™ Tip Syringes is demonstrated as tested per ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications.*

Non-Clinical Tests:

1. Ink Adhesion
2. Visual Inspection, including (burrs, hooks, cracks, foreign contamination, missing components)
3. NRFit Associated Device Testing
4. NRFit Device Interconnectibility
5. Pressure/Injection Testing
6. Tolerance on Graduated Capacity per ISO 7886-1:2017
7. Determination of Dead Space per ISO 7886-1:2017

8. Liquid Leakage at Syringe Piston under Compression per ISO 7886-1:2017
9. Force to Operate Piston per ISO 7886-1:2017
10. Fit of Piston within Barrel per ISO 7886-1:2017
11. Leakage Under Pressure/During Aspiration per ISO 7886-1:2017
12. Stress Cracking per ISO 80369-20:2015 with conformance to ISO 80369-6:2016
13. Fluid Leakage by Pressure Decay per ISO 80369-20:2015 with conformance to ISO 80639-6:2016
14. Subatmospheric Leakage per ISO 80369-20:2015 with conformance to ISO 80369-6:2016
15. Resistance to Separation from Unscrewing per ISO 80369-20:2015 with conformance to ISO 80369-6:2016
16. Resistance to Separation from Axial Load per ISO 80369-20:2015 with conformance to ISO 80369-6:2016
17. Resistance to Overriding per ISO 80369-20:2015 with conformance to ISO 80369-6:2016
18. Particulate Matter per USP <788>

Biocompatibility testing has demonstrated the subject devices [externally communicating device, indirect blood path with limited (≤24 hours) duration] meet the guidelines as described in the FDA guidance document entitled, "Use of International Standard ISO 10993-1; Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."

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 non-clinical tests

Conclusion:

The materials, intended use, technological and operational characteristics of the subject devices are substantially equivalent to the predicate TOP syringes of K843414 and the neuraxial syringes cleared in K170218.