DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2017

Terumo Europe N.V.
Mrs. M.J. Aerts
Regulatory Affairs Manager
Interleuvenlaan 40
3001 Leuven
BELGIUM

Re: K161606
Trade/Device Name: Syringe with fixed needle – For use only with GONAL-f Multi-Dose 600IU/mL FSH
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF,FMI
Dated: December 22, 2016
Received: January 11, 2017

Dear Mrs. M.J. Aerts:

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" (21CFR 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,

Tina Kiang
-S

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K161606

Device Name
Syringe with fixed needle - For use only with GONAL-f Multi-Dose 600 IU/mL FSH

Indications for Use *(Describe)*
The "Syringe with fixed needle - For use only with GONAL-f Multi-Dose 600 IU/mL FSH" is a hypodermic syringe with fixed needle intended for manual aspiration of GONAL-f Multi-Dose and for the injection of this solution into parts of the body below the surface of the skin.

The syringes designed for manual use are intended for use soon after filling, as they are not suitable for containing GONAL-f Multi-Dose over extended periods of time.

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."*

## II. 510(k) SUMMARY as required by 807.92 (K161606)

### Submitter Information


Prepared for: TERUMO EUROPE N.V.
Interleuvenlaan 40,
3001 Leuven,
BELGIUM

Prepared by: Mrs. M.J. Aerts – Manager Regulatory Affairs
Tel. (+32) 16 38 13 53
Fax (+32) 16 40 02 49


Date prepared: February 9, 2017

### II.1. Device Name

Proprietary Name: Syringe with fixed needle - For use only with GONAL-f Multi-Dose 600 IU/mL FSH

Common Name: Hypodermic syringe with a fixed hypodermic single lumen needle

Regulation Name: Piston syringe

Regulation Number: 880.5860

Product Code: FMF,FMI

Review Panel: General Hospital

Classification: Class II

### II.2. Predicate Device

Proprietary Name: Serono GONAL-f Multi-dose Use Only at 600IU/ml Syringe
Regulation Name: Piston Syringe
Regulation Number: 880.5860
Product Code: FMF
Classification: Class II

### II.3. Indications for Use

The “Syringe with fixed needle - For use only with GONAL-f Multi-Dose 600 IU/mL FSH” is a hypodermic syringe with fixed needle intended for manual aspiration of GONAL-f Multi-Dose and for injection of this solution into parts of the body below the surface of the skin.

The syringes designed for manual use are intended for use soon after filling, as they are not suitable for containing GONAL-f Multi-Dose over extended periods of time.

### II.4. Description

The “Syringe with fixed needle – For use only with GONAL-f Multi-Dose 600 IU/mL FSH” is comprised of a standard piston syringe with a permanently attached (fixed) hypodermic single lumen needle designed for the manual aspiration and injection of GONAL-f Multi-Dose. The needle is covered by a protective cap. The graduated scale is specifically designed for GONAL-f Multi-Dose. This syringe is a 1 ml syringe with 27G x ½” fixed needle. This is a single use syringe.

II.5. Substantial Equivalence

| | Syringe with fixed needle – For use only with GONAL-f Multi-Dose 600 IU/mL FSH (Terumo Europe, Belgium) (Subject of this 510k) | Syringe – Use only with GONAL-f Multi-dose at 600IU/ml (Terumo Medical Corporation) (K003571) (Predicate device) |
|---|---|---|
| Indications for Use | The "Syringe with fixed needle - For use only with GONAL-f Multi-Dose 600 IU/mL FSH" is a hypodermic syringe with fixed needle intended for manual aspiration of GONAL-F Multi-Dose and for the injection of this solution into parts of the body below the surface of the skin.<br><br>The syringes designed for manual use are intended for use soon after filling, as they are not suitable for containing GONAL-f Multi-Dose over extended periods of time | The Serono Gonal-f Multi-dose only at 600IU/ml syringe is intended for manual aspiration of Gonal-f Multi-dose only at 600 IU/ml and for the injection of this solution into body parts below the surface of the skin. The syringe is designed for manual use. It is specifically indicated for the Gonal-f Multidose only solutions manufactured by Serono Lab. |
| Materials<br>Plunger<br>Cannula<br>Protector<br>Barrel<br>Gasket<br>Lubricant<br>Printing | <br>Polypropylene + Masterbatch White<br>Stainless steel<br>Polypropylene + Masterbatch White<br>Polypropylene<br>Thermoplastic elastomer<br>Silicone<br>Black ink | <br>Polystyrene<br>Stainless steel<br>HD-Polyethylene + Masterbatch White<br>Polypropylene<br>Thermoplastic elastomer<br>Silicone<br>Black ink |
| Description /Specifications | Same as predicate | A standard piston syringe made of a plastic barrel and plunger and a synthetic rubber gasket. |
| Needle Gauge/length | Same as predicate | 27G x ½" |
| Principle of Operation | Same as predicate | Manually |
| Unit packaging | Same as predicate | Blister packaging |
| Sterilization | EtO to SAL $10^{-6}$ | Gamma irradiation to SAL $10^{-6}$ |
| Shelf life | Same as predicate | 5 years |

Most characteristics are similar or identical.

There are some minor differences in the indications for use. The language has been updated to clearly state how the device is to be used and to indicate that the device should not to be used for storage of GONAL-f. These updates do not change the intended use of the device.

There are some differences in materials for the plunger and the protector, however polypropylene used for the proposed device is a well-known polymer material for medical applications, as are polystyrene and polyethylene used for the predicate device. The sterilization method is different, however SAL $10^{-6}$ is guaranteed by both EtO for the proposed device and gamma irradiation for the predicate device.

The differences do not raise questions of safety and effectiveness

II.6. Summary of Verification Activities

All necessary verification and validation tests have been performed by testing the "Syringe with fixed needle - For use only with GONAL-f Multi-Dose 600 IU/mL FSH". Summary of the verification activities including acceptance criteria is given in the table below:

| TEST | STANDARD OR INTERNAL ACCEPTANCE CRITERIA |
|---|---|
| 1. Cleanliness and visual appearance | Cleanliness and visual appearance in accordance with EN ISO 8537. |

| | |
|---|---|
| 2. Position of gasket | The gasket is assembled so that the fiducial line is positioned at 3 mm +1/-3 mm from the zero-line of the graduation in accordance with internal acceptance criteria. |
| 3. Effective needle length | Effective needle length needs to be between 10 and 14 mm in accordance with internal acceptance criteria. |
| 4. Blister dimension + seal width | The dimension of the blister pack is in accordance with the technical drawing (LxW: 150 x 34.3 mm). The seal width of the blister pack is minimum 2 mm. This is in accordance with internal acceptance criteria. |
| 5. Peel behavior | Peel behavior in accordance with EN ISO 11607-1. |
| 6. Sterile barrier system integrity | Sterile barrier system integrity in accordance with EN ISO 11607-1. |
| 7. Peel strength | Peel strength in accordance with EN ISO 11607-1. |
| 8. Seal strength | Seal strength in accordance with EN ISO 11607-1. |
| 9. Package burst | Package burst test in accordance with EN ISO 11607-1. |
| 10. Air leakage past gasket and needle/barrel connection | No leakage of air past the gasket and needle/barrel connection in accordance with EN ISO 8537. |
| 11. Liquid leakage past gasket and needle/barrel connection | No leakage of water past the gasket and needle/barrel connection in accordance with EN ISO 8537. |
| 12. Mobility Force | The Initial Force is maximum 10 N and the Emptying Force is maximum 1.0 N in accordance with internal acceptance criteria. |
| 13. Tolerance on graduated capacity | Tolerance on graduated capacity is in accordance with EN ISO 8537 |
| 14. Dead space volume | Dead space volume in accordance with EN ISO 8537. |
| 15. Plunger-gasket assembly fitting | The gasket-plunger does not separate in accordance with internal acceptance criteria. |
| 16. Stopper function strength | The stopper function strength is more than 10 N in accordance with internal acceptance criteria. |
| 17. Barrel printing resistance | To check the readability of the graduated printing of syringes after contact with water, ethanol, oil, antiseptic solution or tension-active solution, or after pencil scratching or dry rubbing with finger. This is in accordance with internal acceptance criteria. |
| 18. Protector fitting strength | The protector fitting strength is between 2 N and 12 N in accordance with internal acceptance criteria. |
| 19. Bonding strength cannula | Bonding strength of the cannula in accordance with EN ISO 8537. |
| 20. Needle penetration resistance | The penetration resistance of cannula point and drag complies with the limits specified as follow: Point Value ≤ 0.12 N and Drag Value ≤ 0.04 N. This is in accordance with internal acceptance criteria. |
| 21. Transport simulation test | There is no damage of the sterile barrier after vibration test (in accordance with EN ISO 2247), roll test (in accordance with EN ISO 2876) and vertical impact test (in accordance with drop test) (in accordance with EN ISO 2248). |

II.7. Additional Information

The sterility of the “Syringe with fixed needle – For use only with GONAL-f Multi-Dose 600 IU/mL FSH” is assured by using a validated sterilization method qualified in accordance with EN ISO 11135: “Sterilization of health care products – Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices” to a sterility assurance level (SAL) of $10^{-6}$
Ethylene oxide and ethylene chlorohydrin residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: “Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals”. The shelf life has been established at 5 years.

The “Syringe with fixed needle – For use only with GONAL-f Multi-Dose 600 IU/mL FSH” is an External Communicating device, Contacting Circulating Blood, Limited Exposure (≤ 24 hrs). The device’s blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard EN ISO-10993-1, “Biological Evaluation of Medical Devices. Part-1:

Evaluating and testing within a risk management process". The following biocompatibility tests have been performed:

- cytotoxicity (in accordance with EN ISO 10993-5),
- haemolysis (in accordance with EN ISO 10993-4),
- systemic (acute) toxicity (in accordance with EN ISO 10993-11),
- intracutaneous reactivity (in accordance with EN ISO 10993-10),
- sensitization (in accordance with EN ISO 10993-10),
- pyrogenicity
- LAL Testing

Results of the testing demonstrate that the blood contacting materials are biocompatible.

II.8. Conclusion

In summary, the "Syringe with fixed needle – For use only with GONAL-f Multi-Dose 600 IU/mL FSH" is substantially equivalent in intended use, description/specifications, technology/principal of operation, materials, and performance to the following cleared device: "Serono GONAL-f Multi-dose Use Only at 600IU/ml Syringe", manufactured by Terumo Medical Corporation (K003517).