March 2, 2018

Astell Scientific Limited
Gary Doughty
Quality and Compliance Manager
19-21 Powerscroft Rd
Sidcup, Kent
DA14 5DT
United Kingdom

Re: K170304
Trade/Device Name: Astell UMB 220, UMB 230, UMB 240 Autoclaves/Sterilizers
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: January 24, 2018
Received: January 26, 2018

Dear Gary Doughty:

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.

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.

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,

Michael J. Ryan -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

# Indications for Use

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

510(k) Number *(if known)*
K170304

Device Name
Astell UMB 220, UMB 230, UMB 240 Autoclaves/sterilizers

Indications for Use *(Describe)*
A steam sterilizer (Autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.

Typical applications:

Metal Medical Instruments (Unwrapped)
Metal Medical Instruments (Wrapped)
Glassware (Unwrapped)
Hand Pieces (Pouches)

The electronic control has four pre-programmed sterilization cycles.

The four pre-programmed sterilization cycles are for:

Cycle 1; Metal Medical Instruments (Unwrapped); 134°C for 3 minutes; Drying Time 15 minutes

Cycle 2; Metal Medical Instruments (Wrapped); 134°C for 4 minutes; Drying time 30 minutes

Cycle 3; Glassware (Unwrapped); 121°C for 30 minutes; Drying time 15 minutes

Cycle 4; Hand pieces; (Pouches) 134°C for 4 minutes; Drying time 15 minutes

The four pre-programmed cycles are for:

Cycle 1; Metal Medical Instruments (Unwrapped); 134°C for 3 minutes; Drying Time 15 minutes
Maximum Load: Shelf rack can accommodate 4 instrument trays instruments they have to be layered down in an open position. All instruments have to remain apart with a minimum distance of 1 cm. Maximum weight/tray: 2.5 kg, Maximum load/cycle: 10 kg

Cycle 2; Metal Medical Instruments (Wrapped); 134°C for 4 minutes; Drying time 30 minutes
Maximum Load: Shelf rack can accommodate 2 pouch racks. Pouches have to stand on their side and not touching each other. Leave at least 2 cm between each item. Maximum weight/rack: 2.5 kg Maximum load/cycle: 5 kg

Cycle 3; Glassware (Unwrapped); 121°C for 30 minutes; Drying time 15 minutes
Shelf rack can accommodate 4 trays. Glassware have to be placed upside down with a minimum distance of 1 cm. Maximum weight/tray: 2.5 kg Maximum load/cycle: 10 kg

Cycle 4; Hand pieces; (Pouches) 134°C for 4 minutes; Drying time 15 minutes
Maximum Load: Shelf rack can accommodate 2 pouch racks. Pouches have to stand on their side and not touching each other. Leave at least 2 cm between each item. Maximum weight/rack: 2.5 kg Maximum load/cycle: 5 kg.

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."*

Astell Scientific Ltd
Powerscroft Road
Sidcup, Kent
DA14 5DT
United Kingdom

Tel: 0208 309 2031
Fax: 0208 300 2247

e-mail: info@astell.com
website: http://www.astell.com

# 510(K) Number K170304 Summary

**Submitter:**

Astell Scientific Limited
19-21 Powerscroft Road
Sidcup
Kent
DA14 5DT

Telephone: +44 020 8309 2003
Email: gdoughty@astell.com

**Contact:** G Doughty

**Date:** 28TH February 2018

**Common Name:** Steam Sterilizer

**Product Code:** FLE

**Device Trade Name:** Astell UMB 220, UMB 230, UMB 240 Autoclaves/Sterilizers

**Classification Name:** Steam Sterilizer: Class II Device-21 C.F.R. § 880.6880

**Predicate Device 510(k) No:** K111736

**Predicate Device Trade Name:** Tuttnauer EZ Plus Series Electronic Table Top Autoclaves (EZ9 Plus, EZ11 Plus, EZ 15 Plus.

**Classification Name:** Steam Sterilizer Class II Device-21 C.F.R § 880.6880

**General Description /Technology:**

The Astell Scientific range of UMB benchtop steam sterilizers are designed to offer convenience and flexibility in the sterilization of medical and surgical instruments.

Instruments for sterilization include wrapped and unwrapped Metal Medical instruments, unwrapped Glassware and pouched dental hand pieces.

A steam sterilizer (Autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam. Autoclaves/sterilizers heat water to generate steam as the sterilization agent, producing steam in the chamber to create a gravity displacement, pulsed dynamic air removal sterilization environment.

Steam sterilization is a widely used sterilization process due to its versatility and speed. The sterilizers include as its main components a pre-programmed electronic control module, autofill water reserve, electronic heaters and an auto-drain sterilization chamber.

The free-steaming phase of the sterilization process incorporates a 20-minute dynamic air removal program pulsing at low; 1200 mbar/ high;1600 mbar

The autoclaves are equipped with multiple safety features. The door contains a safety locking mechanism that does not permit operation unless the door is closed and locked, and does not permit the door to be opened until the internal chamber pressure is no greater than 100mbar above atmospheric pressure. Additional safety features include an automatic safety shutoff to prevent the chamber overheating; two (2) thermostats; one to detect overheating of the heaters and one to prevent opening of the door if the chamber temperature is unsafe to do so (80 °C). There is also a safety valve for the pressure vessel.

A touch screen digital display with a user log, data archiving for up to 5000 cycles and multiple user access levels and multi-level password protection is used for precision control and monitoring purposes.

The differences between the UMB Autoclaves/Sterilizers in this submission is the chamber volumes:

UMB 220 (Total volume 33 Litres)
UMB 230 (Total volume 43 Litres)
UMB 240 (Total volume 63 Litres)

There is an optional printer available to record cycle parameters.

Only United States Food and Drug Administration cleared accessories such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes should be used with this Autoclave.

**Design and Materials:**

Astell Scientific Autoclaves are designed and manufactured in accordance with the requirements of European Medical Devices Directive 93/42/EEC, BS EN 13060:2014, ANSI/AAMI ST55:2010 and the appropriate Pressure Vessel Directive 2014/68/EU or ASME Boiler and Pressure Vessel Code Rules, Section VIII, Division 1. The manufacturing principles specified in these directives and standards are followed for the products in this submission.

The UMB range of Autoclaves sterilization chamber is manufactured from Stainless Steel Grade 316 with the internal bore electro polished. The range are fitted with electronic heating elements, an autofill water reservoir and an electronic control system. The control system is pre-programmed

with four sterilization cycles and up to a further 50 cycles available. There is also a safety valve test cycle.

**Non-Clinical Testing:**

The Astell Scientific range of Autoclave/Sterilizers within this submission are certified by a Notified Body (SGS) to be compliant with the requirements of MDD 93/42/EEC inclusive of BS EN 13060:2014, similar in scope and content to the requirements of AAMI/ANSI ST55:2010.

All testing was conducted in accordance with the requirements of AAMI/ANSI ST55:2010 inclusive of physical and microbiological performance requirements.

Model UMB240 have a total capacity of 63 litres which is larger than the 56.63 litre specification of AAMI/ANSI ST55:2010. The useable capacity of this model is 50 litres. It is therefore considered they should be evaluated as compliant with the capacity specification of AAMI/ANSI ST55:2010.

There are not any patient contacting components within this range of Autoclaves/Sterilizers.

When used as intended by competent trained personnel any patient contact will be with sterilized products.

**Indications for use.**

A steam sterilizer (Autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.

Typical applications include:

Metal Medical Instruments (Unwrapped)
Metal Medical Instruments (Wrapped)
Glassware (Unwrapped)
Hand pieces (Pouches)

The electronic control has four pre-programmed sterilization cycles.

The four pre-programmed cycles are for:

Cycle 1; Metal Medical Instruments (Unwrapped); 134°C for 3 minutes; Drying Time 15 minutes
Maximum Load: Shelf rack can accommodate 4 instrument trays instruments they have to be layered down in an open position. All instruments have to remain apart with a minimum distance of 1 cm. Maximum weight/tray: 2.5 kg, Maximum load/cycle: 10 kg

Cycle 2; Metal Medical Instruments (Wrapped); 134°C for 4 minutes; Drying time 30 minutes
Maximum Load: Shelf rack can accommodate 2 pouch racks. Pouches have to stand on their side and not touching each other. Leave at least 2 cm between each item. Maximum weight/rack: 2.5 kg
Maximum load/cycle: 5 kg

Cycle 3; Glassware (Unwrapped); 121°C for 30 minutes; Drying time 15 minutes
Shelf rack can accommodate 4 trays. Glassware have to be placed upside down with a minimum distance of 1 cm. Maximum weight/tray: 2.5 kg Maximum load/cycle: 10 kg

Cycle 4; Hand pieces; (Pouches) 134°C for 4 minutes; Drying time 15 minutes
Maximum Load: Shelf rack can accommodate 2 pouch racks. Pouches have to stand on their side and not touching each other. Leave at least 2 cm between each item. Maximum weight/rack: 2.5 kg
Maximum load/cycle: 5 kg.

**Technical Standards:**

The Astell Scientific UMB series of autoclaves have been assessed to be compliant with the requirements of the following FDA recognised standards:

**ANSI/AAMI ST55:2010: Tabletop Steam Sterilizers**

BS EN 13060 is the European equivalent of ANSI/AAMI ST55:2010. The Astell range of AMB/UMB sterilizers have been certified by SGS as compliant with BS EN 13060. Astell conducted additional testing to the following ANSI/AAMI ST55:2010 specifications:

5.4.3; Sterilizer temperature control
5.5 Biological performance of sterilizers
5.6 Mechanical air removal
5.7 Moisture retention
5.8 Sterilizer performance certification and record keeping.

**IEC 61010:2010: Electrical safety for laboratory equipment**

EN 61010-1 1993/A2:1995; Report 071-607596-00; Test date 05/15/2002

IEC 61010:2010; Report 071-75934461-000; Test date 05/06/2016

IEC 61010:2010; Report 071-071-75935721; Test date 08/08/2016

The above tests were conducted on 50L useable volume sterilizers. The models with a useable volume of 50 litres are AMB/UMB 240 Total volume 63L.

Models UMB 220, 230 and 240 are electrically identical (utilizing the same electrical components).

Original compliance testing report 071-607596-00 was conducted to EN 61010-1 1993/A2:1995. Test reports 071-75934461-000 and 071-071-75935721 are gap analysis reports to demonstrate compliance with IEC 61010:2010. Testing was only conducted on the elements which had changed in the standard revision process.

The original test report and the subsequent gap analysis reports demonstrate all models in this application are compliant with the content of IEC 61010:2010.

**IEC 61010-2-040: Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements for sterilizers and washer-disinfectors used to treat medical materials**

Particular requirements for sterilizers and washer-disinfectors used to treat medical materials is an element within the Medical Devices Directive 93/42 EEC. Compliance is demonstrated by self-certification completion of an Electrical Safety checklist validated by Notified Body SGS.

**IEC 61326:2013: Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements**

EMC testing in accordance with the requirements of IEC 61326:2013

EN 61326-1:2006; Report 02-556/3886/1/09; Test date 16th – 23 February 2009

EN 61326-1:2013; Report 04/8557-2-16; Test date 13th April 2016

The above tests were conducted on AMB/UMB 230 with a total volume of 43L and an AMB/UMB 220 with a total volume of 33L.

Models UMB 220, 230 and 240 are electrically identical (utilizing the same electrical components).

Original compliance testing report 02-556/3886/1/09 was conducted to EN 61326-1:2006. Test report 04/8557-2-16 is a gap analysis to demonstrate compliance with EN 61326-1:2013. Testing was only conducted on the elements which had changed in the standard revision process.

The original test report and the subsequent gap analysis report demonstrates all models in this application are compliant with the content of EN 61326-1:2013.

**BS EN ISO 14971:2012: Application of Risk Management to Medical Devices**

Particular requirements for sterilizers and washer-disinfectors used to treat medical materials is an element within the Medical Devices Directive 93/42 EEC. Compliance is demonstrated by self-certification completion of an Electrical Safety checklist validated by Notified Body SGS.

**IEC 62366:2015: Application of Usability to Medical Devices**

Requirements for Medical Devices is an element within the Medical Devices Directive 93/42 EEC. Compliance is demonstrated by self-certification completion of an Electrical Safety checklist validated by Notified Body SGS.

**IEC 62304: 2006: Software Life Cycle Processes**

Requirements for Medical Devices is an element within the Medical Devices Directive 93/42 EEC. Compliance is demonstrated by self-certification completion of an Electrical Safety checklist validated by Notified Body SGS.

**Technical Directives**

Medical Devices Directive; 93/42/EEC

Pressure Equipment Directive 2014/68/EU

**Quality Management Systems**

Astell Scientific's Quality Management system is compliant with the following standards which are annually audited by Notified Body SGS.

ISO EN 13485: 2012

ISO 9001:2008

## Technological Characteristics Comparison Tables

**Table 1; Technological characteristics Comparison**

| Description | K170304 | K111736 | Substantially Equivalence Comparison |
|---|---|---|---|
| Sterilization cycles operate by gravity displacement | Yes | Yes | Same |
| Sterilizing Medical and Surgical goods | Yes | Yes | Same |
| 316 Stainless Steel Chamber | Yes | Yes | Same |
| Chamber Diameter | 13.8” | 9”-15” | Similar |
| Chamber Depth | 14.2-26” | 19.8-30” | Similar |
| Chamber Volume Range | 8.7 -16.6 US Gal | 5.2-22 US Gal | Similar |
| Pre-programmed Sterilization Cycles | 4 | 4 | Same |
| Electrically generated steam | Yes | Yes | Same |
| Multiple Safety Features | Yes | Yes | Same |
| Door Safety Locking Mechanism | Yes | Yes | Same |
| Automatic Safety Shutoff | Yes | Yes | Same |
| Two overheating Thermostats | Yes | Yes | Same |
| Safety Pressure Valve | Yes | Yes | Same |
| Digital Display | Yes | Yes | Same |
| Optional Printer | Yes | Yes | Same |

**Table 2; volumetric characteristics Comparison**

| Model | Capacity (Litres) | Chamber (Dia x Depth-mm) | Model | Capacity (Litres) | Useable Capacity (Litres) | Chamber (Dia x Depth-mm) | Substantially Equivalence Comparison |
|---|---|---|---|---|---|---|---|
| EZ9 Plus | 19.8 | 230 x 504 | UMB 220 | 33 | 23 | 350 x 360 | Similar |
| EZ11 Plus | 28.5 | 280 x 504 | UMB 230 | 43 | 33 | 350 x 460 | Similar |
| EZ15 Plus | 84 | 380 x 760 | UMB 240 | 63 | 50 | 350 x 660 | Similar |

**Table 3A; Tuttnauer Indication for Use**

| K111736 | | | | | |
|---|---|---|---|---|---|
| **Recommended Use** | **Device functions** | **Sterilization Temperature** | **Sterilization Time (Minutes)** | **Dry Time** | **Substantially Equivalence** |
| Instruments (Unwrapped) | EZ9 (G)<br>EZ11 (1A)<br>EZ15 (1A) | 132°C | 3 | 1 | Similar |
| Instruments (Wrapped) | EZ9 (1A)<br>EZ11 (1A)<br>EZ15 (1A) | 132°C | 4 | 30 | Similar |
| Glassware (Unwrapped) | EZ9 (G)<br>EZ11 (1A)<br>EZ15 (1A) | 121°C | 30 | 1 | Similar |
| Hand pieces | EZ9 (7A)<br>EZ11 (7A)<br>EZ15 (5A) | 132°C | 4 | 30 | Similar |

(G) = Gravity displacement: (A) = Dynamic Air Removal Pulse

**Table 3B; Astell Indications for Use**

| K170304 | | | | | | |
|---|---|---|---|---|---|---|
| **Recommended Use** | **Device functions** | **Sterilization Temperature** | **Sterilization Time (Minutes)** | **Dry Time** | **Substantially Equivalence Comparison** | **Maximum Load** |
| Metal Medical Instruments (Unwrapped) | UMB 220 (P) UMB 230 (P) UMB 240 (P) | 134°C | 3 | 15 | Similar | Shelf rack can accommodate 4 instrument trays instruments they have to be layered down in an open position. All instruments have to remain apart with a minimum distance of 1cm. Maximum weight/tray: 2.5kg Maximum load/cycle: 10 kg. |
| Metal Medical Instruments (Wrapped) | | 134°C | 4 | 30 | Similar | Shelf rack can accommodate 2 pouch racks. Pouches have to stand on their side and not touching each other. Leave at least 2cm between each item Maximum weight/rack: 2.5 kg Maximum load/cycle: 5 kg. |
| Glassware (Unwrapped) | | 121°C | 30 | 15 | Similar | Shelf rack can accommodate 4 trays. Glassware have to be placed upside down with a minimum distance of 1 cm Maximum weight/tray: 2.5kg Maximum load/cycle: 10 kg. |
| Hand pieces (Pouches) | | 134°C | 4 | 30 | Similar | Shelf rack can accommodate 2 pouch racks. Pouches have to stand on their side and not touching each other. Leave at least 2cm between each item Maximum weight/rack: 2.5 kg Maximum load/cycle: 5 kg. |

**Table 4: Technical Standards Comparison**

| **Standard Title** | **K170304** | **K111736** | **Substantially Equivalence** |
|---|---|---|---|
| ANSI/AAMI ST55:2010 | ✓ | ✓ | Same |
| ASME Section VIII Division 1 | ✓ | ✓ | Same |
| IEC 61010:2010 | ✓ | ✓ | Same |
| IEC 61010-2-040 | ✓ | ✓ | Same |
| IEC 61326:2013 | ✓ | X | Similar |
| BS EN ISO 14971:2012 | ✓ | X | Similar |
| IEC 62366:2015 | ✓ | X | Similar |
| IEC 62304: 2006 | ✓ | X | Similar |
| ISO EN 13485: 2012 | ✓ | ✓ | Same |
| ISO 9001:2008 | ✓ | ✓ | Same |
| Canada Standards: CMDR | X | ✓ | Same |
| ISO 17665-1:2006 | X | ✓ | Same |

**Table 5: Thermal Profiling Comparison**

| Sterilization Temperature Tolerance | K170304 | K111736 | Substantially Equivalence Comparison |
|---|---|---|---|
| -0°c and + 3°c | Cycle 121°c; Passed | Cycle 121°c; Passed | Same |
| -0°c and + 3°c | Cycle 134°c Passed | Cycle 132°c; Passed | Similar |

**Conclusion:**

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well or better than the legally marketed predicate device, K111736