



Food and Drug Administration
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Silver Spring, MD 20993-0002

February 23, 2017

Cefla S.C.
c/o Maurizio Pantaleoni
ISEMED srl
Via Altobelli Bonetti 3/A
Imola, Bologna 40026
ITALY

Re: K161848

Trade/Device Name: Family of Steam Sterilizers B17 B22 Series
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: January 15, 2017
Received: January 18, 2017

Dear Maurizio Pantaleoni:

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,

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

510(k) Number (if known)
K161848

Device Name
Family of Steam sterilizers B17 B22 series

Indications for Use (Describe)

B CLASSIC-17 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

Program description, cycle times, temperature and dry time are described in the table below:

B CLASSIC-17 model

Chamber Dimensions (Depth 350mm / Diameter 250mm / Volume about 17 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Classic-17</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	12.75 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	12.75 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	12.75 min	4 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.5 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

B CLASSIC-17 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

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.

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Indications for Use

510(k) Number (if known)
K161848

Device Name
Family of Steam sterilizers B17 B22 series

Indications for Use (Describe)

B CLASSIC-22 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

Program description, cycle times, temperature and dry time are described in the table below:

B CLASSIC-22 model

Chamber Dimensions (Depth 450mm / Diameter 250mm / Volume about 22 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Classic-22</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	14.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	14.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	14.5 min	4.50 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4.50 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.5 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

B CLASSIC-22 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

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)

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Indications for Use

510(k) Number (if known)
K161848

Device Name
Family of Steam sterilizers B17 B22 series

Indications for Use (Describe)

B FUTURA-17 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

Program description, cycle times, temperature and dry time are described in the table below:

B FUTURA-17 model

Chamber Dimensions (Depth 350mm / Diameter 250mm / Volume about 17 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Futura-17</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	9.67 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	9.67 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	9.67 min	4 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.33 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

B FUTURA-17 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

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Indications for Use

510(k) Number (if known)
K161848

Device Name
Family of Steam sterilizers B17 B22 series

Indications for Use (Describe)

B FUTURA-22 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

Program description, cycle times, temperature and dry time are described in the table below:

B FUTURA-22 model

Chamber Dimensions (Depth 450mm / Diameter 250mm / Volume about 22 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Futura-22</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	11.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	11.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	11.5 min	4.50 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4.50 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.33 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

B FUTURA-22 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

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)

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510(k) Summary

Family of Steam sterilizers B17 B22 series

K161848

2.1. General Information

Submitter: CEFLA S.C.
Via Selice Provinciale, 23/A
40026 - IMOLA (BO)
ITALY

Establishment Registration Number: 3006610845

Contact Person in Italy: Maurizio Pantaleoni
ISEMED srl
Via Altobelli Bonetti 3/a
40026 Imola (BO)
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Mob.phone: +39-348 4435155
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Fax: +39-542 698456
Email: regulatory@isemed.eu

Summary Preparation Date: February 15, 2017

2.2. Names

Device Name: Family of Steam sterilizer B17 B22 series
Classification Name: Steam Sterilizer
Product Code: FLE
Regulation number: 880.6880
Class: II

2.3. Predicate Devices

The Family of steam sterilizers B17 B22 series is substantially equivalent to the following legally marketed predicate device:

<i>Applicant</i>	<i>Device name</i>	<i>510(k) Number</i>
CEFLA S.C.	Family of steam sterilizers B28 series	K151597

2.4. Indications for Use

B CLASSIC-17 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

B CLASSIC-17 model

Chamber Dimensions (Depth 350mm / Diameter 250mm / Volume about 17 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Classic-17</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	12.75 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	12.75 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	12.75 min	4 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.5 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

Table 1 – B CLASSIC-17 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

B CLASSIC-22 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

B CLASSIC-22 model

Chamber Dimensions (Depth 450mm / Diameter 250mm / Volume about 22 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**)(***)
<u>B Classic-22</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	14.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	14.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	14.5 min	4.50 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4.50 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar)	134°C / 273°F 3.5 minutes	1.5 min	Test device only (without another load)

	each step)			
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

Table 3 – B CLASSIC-22 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased
 (**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).
 Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$
 (***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)
 (****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

B FUTURA-17 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

B FUTURA-17 model

Chamber Dimensions (Depth 350mm / Diameter 250mm / Volume about 17 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Futura-17</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	9.67 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121 (3 prevacuum steps; -0.8 bar each step)	121°C / 250°F 20 minutes	9.67 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.6 kg unwrapped porous and fabric textiles 0.5 kg single package porous and fabric textiles 0.4 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	9.67 min	4 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2 kg single package metal or polymer instruments (max 1.33 kg per tray)

	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.33 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

Table 2 – B FUTURA-17 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

B FUTURA-22 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process.

The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.

B FUTURA-22 model

Chamber Dimensions (Depth 450mm / Diameter 250mm / Volume about 22 liters)

MODEL NAME	CYCLE NAME	STERILIZATION TEMPERATURE / EXPOSURE TIME	DRYING TIME (*)	DESCRIPTION OF MAXIMUM LOAD AND TYPE (**) (***)
<u>B Futura-22</u>	(C1) UNIVERSAL 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	11.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C2) UNIVERSAL 121	121°C / 250°F 20 minutes	11.5 min	4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments

	(3 prevacuum steps; -0.8 bar each step)			and dental handpieces (max 1.33 kg per tray) 1.25 kg double package metal or polymer instruments and dental handpieces (max 1.33 kg per tray) 0.75 kg unwrapped porous and fabric textiles 0.60 kg single package porous and fabric textiles 0.50 kg double package porous and fabric textiles
	(C4) SOLID 134 (1 prevacuum step; -0.8 bar)	134°C / 273°F 4 minutes	11.5 min	4.50 kg unwrapped metal or polymer instruments (max 1.33 kg per tray) 2.25 kg single package metal or polymer instruments (max 1.33 kg per tray)
	(C5) HOLLOW 134 (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 4 minutes	3 min	4.50 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33 kg per tray)
	HELIX/BD TEST (3 prevacuum steps; -0.8 bar each step)	134°C / 273°F 3.5 minutes	1.33 min	Test device only (without another load)
	VACUUM TEST (-0.8 bar)	/	/	Empty chamber Vacuum -0.8 bar Test Time: 27 min
	VACUUM + HELIX/BD TEST (****)	/	/	/

Table 4 – B FUTURA-22 Factory programmed sterilization cycles and parameters

(*) Default drying time, but the drying time can be manually increased

(**) Cycles C1, C2 are validated to sterilize up to 6 single sided lumened devices with inner diameter/length of the lumen: $\geq 1.25 \text{ mm} / \leq 118 \text{ mm}$ (corresponding to “hollow A” cavities with a length/diameter (L/D) ratio = $1 \leq L/D \leq 750$).

Cycles C4 and C5 are validated to sterilize up to 6 double sided lumened devices with inner diameter/length of the lumen: $\geq 10 \text{ mm} / \leq 115 \text{ mm}$

(***) If the material is sterilized “unwrapped” the sterilized material shall used immediately after sterilization (the cycle shall be considered as immediate use cycle)

(****) This program enables to execute, in sequence, Vacuum test and Helix/BD test (nevertheless each test is executed separately)

2.5. Device Description

The Family of steam sterilizers B17 B22 series includes table-top steam sterilizers that use saturated steam at high pressures and temperatures to kill infectious bio-organisms. The Classic and B Futura models differ only for some minor characteristics such as color touchscreen, optional Wi-Fi connection, illumination of the working area and Ethernet connection.

The steam is generated by a steam generator connected to the sterilization chamber without disconnecting devices. An electric heating element surrounds the chamber for preheating of the chamber and maintaining the temperature. The subject family is characterized by a fractionated vacuum system for the complete air removal also from hollow and porous materials as well as by a final vacuum drying phase able to eliminate any trace of condensation from the load.

Nonclinical Comparison to Predicate Devices.

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Regulation number	880.6880 – Steam Sterilizers	880.6880 – Steam Sterilizers	880.6880 – Steam Sterilizers	Same
Class	II	II	II	Same
Product code	FLE	FLE	FLE	same
Indication for use	<p>B CLASSIC-17 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process. The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.</p> <p>B FUTURA-17 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process. The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.</p>	<p>B CLASSIC-22 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process. The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.</p> <p>B FUTURA-22 is a steam sterilizer that is intended for use by a health care provider (i.e. hospitals, medical and dental practices, clinics, and nursing homes) to sterilize re-usable medical products that are heat and moisture resistant and compatible with the steam sterilization process. The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.</p>	<p>The Family of Steam Sterilizers B 28 series B CLASSIC-28 and B FUTURA-28 models are table top steam sterilizers to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental handpieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.</p> <p>The Family of Steam Sterilizers B 28 series is validated for sterilization of fabric packs/textiles for sterilization programs C1 and C2.</p> <p>The Family of Steam Sterilizers B 28 series is validated for sterilization up to 9 dental handpieces for sterilization programs C1 and C2.</p> <p>The Family of Steam Sterilizers B 28 series is validated for sterilization up to 6 lumen devices</p> <p>The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products</p>	Equivalent
Construction				
Chamber Volume usable	17 litres (10 litres with tray supports inserted)	22 litres (13 litres with tray supports inserted)	28 litres (19 litres with tray supports inserted)	Same
Sterilization Chamber dimensions (Ø x H)	250 x 350 mm	250 x 450 mm	280 x 450 mm	Same
Design				

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Operating principle	The sterilizing agent is steam made from demineralized water. Steam is commonly used to sterilize porous and non porous heat resistant materials / textiles for more than 100 years. Sterilization temperatures are 121°C / 250 °F and 134°C / 273 °F.	The sterilizing agent is steam made from demineralized water. Steam is commonly used to sterilize porous and non porous heat resistant materials / textiles for more than 100 years. Sterilization temperatures are 121°C / 250 °F and 134°C / 273 °F.	The sterilizing agent is steam made from demineralized water. Steam is commonly used to sterilize porous and non porous heat resistant materials / textiles for more than 100 years. Sterilization temperatures are 121°C / 250 °F and 134°C / 273 °F.	Same
Mechanism of action for steam sterilization	Saturated steam contacts the surface of the device and is able to sterilize it, since saturated steam is able to denature the membrane and the proteins of microorganisms and spores. In case of packaged devices or of devices with lumens (e.g. dental handpieces), the steam penetrates through the packaging and into the lumens, by means of the air removal due to the vacuum pump, and is able to sterilize the devices	Saturated steam contacts the surface of the device and is able to sterilize it, since saturated steam is able to denature the membrane and the proteins of microorganisms and spores. In case of packaged devices or of devices with lumens (e.g. dental handpieces), the steam penetrates through the packaging and into the lumens, by means of the air removal due to the vacuum pump, and is able to sterilize the devices	Saturated steam contacts the surface of the device and is able to sterilize it, since saturated steam is able to denature the membrane and the proteins of microorganisms and spores. In case of packaged devices or of devices with lumens (e.g. dental handpieces), the steam penetrates through the packaging and into the lumens, by means of the air removal due to the vacuum pump, and is able to sterilize the devices	Same
Sterilization cycle type	All cycles are pre-vacuum with post vacuum drying	All cycles are pre-vacuum with post vacuum drying	All cycles are pre-vacuum with post vacuum drying	Same
Device SW controlled	Yes	Yes	Yes	Same
Built according to standard	ANSI/AAMI ST55:2010 Table-top steam sterilizers	ANSI/AAMI ST55:2010 Table-top steam sterilizers	ANSI/AAMI ST55:2010 Table-top steam sterilizers	Same
Electrical safety standard	IEC 61010-1:2001 (edition 2) / UL 61010-1 2 nd edition IEC 61010-2-040: 2005 (edition 1) for use in conjunction with IEC 61010-1:2001 (ed. 2)	IEC 61010-1:2001 (edition 2) / UL 61010-1 2 nd edition IEC 61010-2-040: 2005 (edition 1) for use in conjunction with IEC 61010-1:2001 (ed. 2)	IEC 61010-1:2001 (edition 2) / UL 61010-1 2 nd edition IEC 61010-2-040: 2005 (edition 1) for use in conjunction with IEC 61010-1:2001 (ed. 2)	Same
EMC conformity	IEC 61326-1:2012	IEC 61326-1:2012	IEC 61326-1:2012	Same
Heaters	An heating foil pre heats the sterilization chamber and maintains the temperature for the sterilization and drying processes	An heating foil pre heats the sterilization chamber and maintains the temperature for the sterilization and drying processes	An heating foil pre heats the sterilization chamber and maintains the temperature for the sterilization and drying processes	Same
Steam Generator	An external steam generator produces steam through a dedicated heater	An external steam generator produces steam through a dedicated heater	An external steam generator produces steam through a dedicated heater	same
Vacuum Device	FUTURA: Membrane vacuum pump with max free air flow of 20 litres per minute. CLASSIC: Membrane vacuum pump with max free air flow of 7 litres per minute.	FUTURA: Membrane vacuum pump with max free air flow of 38 litres per minute. CLASSIC: Membrane vacuum pump with max free air flow of 20 litres per minute.	FUTURA: Membrane vacuum pump with max free air flow of 38 litres per minute. CLASSIC: Membrane vacuum pump with max free air flow of 20 litres per minute.	Equivalent

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Air filtration	0.027 µm, efficiency: 99.999% efficiency: 99.97% for 0.3- micron particles	0.027 µm, efficiency: 99.999% efficiency: 99.97% for 0.3- micron particles	0.027 µm, efficiency: 99.999% efficiency: 99.97% for 0.3- micron particles	Same
Chamber construction material	Austenitic (304 grade) Stainless Steel or Austenitic (316L grade) Stainless Steel	Austenitic (304 grade) Stainless Steel or Austenitic (316L grade) Stainless Steel	Austenitic (304 grade) Stainless Steel	Equivalent
Chamber design pressure	2.4 bar / 34.8 psi (relative pressure)	2.4 bar / 34.8 psi (relative pressure)	2.4 bar / 34.8 psi (relative pressure)	Same
Chamber design standard	Conforming to ASME BPVC Section 8, Division 2	Conforming to ASME BPVC Section 8, Division 2	Conforming to ASME BPVC Section 8, Division 2	Same
Process parameters / Process Control	Sterilization cycle is controlled by time, temperature and pressure and are recorded on printout. The process is controlled automatically through all the phases of the cycle	Sterilization cycle is controlled by time, temperature and pressure and are recorded on printout. The process is controlled automatically through all the phases of the cycle	Sterilization cycle is controlled by time, temperature and pressure and are recorded on printout. The process is controlled automatically through all the phases of the cycle	Same
Process parameters displayed on control panel:	<u>At cycle start:</u> total number of cycles set Sterilization temperature set Holding time <u>During the cycle:</u> cycle time countdown real time temperature real time pressure. <u>At the end of the cycle:</u> Cycle outcome (positive or negative) min/max temperature during sterilization phase min/max pressure during sterilization phase	<u>At cycle start:</u> total number of cycles set Sterilization temperature set Holding time <u>During the cycle:</u> cycle time countdown real time temperature real time pressure. <u>At the end of the cycle:</u> Cycle outcome (positive or negative) min/max temperature during sterilization phase min/max pressure during sterilization phase	<u>At cycle start:</u> total number of cycles set Sterilization temperature set Holding time <u>During the cycle:</u> cycle time countdown real time temperature real time pressure. <u>At the end of the cycle:</u> Cycle outcome (positive or negative) min/max temperature during sterilization phase min/max pressure during sterilization phase	Same
Process Monitors	<ul style="list-style-type: none"> ✓ 1 temperature probe in the chamber ✓ 1 temperature probe in the heating element ✓ 1 temperature probe in the steam generator ✓ 1 pressure sensor for sterilization chamber ✓ 1 conductivity sensor (water quality) ✓ 1 temperature probe in the reservoir 	<ul style="list-style-type: none"> ✓ 1 temperature probe in the chamber ✓ 1 temperature probe in the heating element ✓ 1 temperature probe in the steam generator ✓ 1 pressure sensor for sterilization chamber ✓ 1 conductivity sensor (water quality) ✓ 1 temperature probe in the reservoir 	<ul style="list-style-type: none"> ✓ 1 temperature probe in the chamber ✓ 1 temperature probe in the heating element ✓ 1 temperature probe in the steam generator ✓ 1 pressure sensor for sterilization chamber ✓ 1 conductivity sensor (water quality) ✓ 1 temperature probe in the reservoir 	Same
Performances				
Biological performance	SAL of 10 ⁻⁶ reduction (no growth at half cycle with validation loads according to AAMI ST55:2010)	SAL of 10 ⁻⁶ reduction (no growth at half cycle with validation loads according to AAMI ST55:2010)	SAL of 10 ⁻⁶ reduction (no growth at half cycle with validation loads according to AAMI ST55:2010)	Same

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Moisture retention	<0.5% increase in wrapped instrument test tray <2% increase in textile test pack according to AAMI ST55:2010	<0.5% increase in wrapped instrument test tray <2% increase in textile test pack according to AAMI ST55:2010	<0.5% increase in wrapped instrument test tray <2% increase in textile test pack according to AAMI ST55:2010	Same
Process equivalent time (F0)	FUTURA 17: 30.14 (F0 at 121°C – worst case condition) CLASSIC 17 30.14 (F0 at 121°C – worst case condition)	FUTURA 22: 29.88 (F0 at 121°C – worst case condition) CLASSIC 22 29.88 (F0 at 121°C – worst case condition)	FUTURA 28: 28.62 (F0 at 121°C – worst case condition) CLASSIC 28 27.70 (F0 at 121°C – worst case condition)	Equivalent
Cycle characteristics				
Cycle phases comparison	The cycle is composed by 9 phases that are: 1) Preheating generator / chamber 2) Vacuum / Steam pulses 3) Temperature increase through pressure raise 4) Temperature and pressure stabilization 5) Sterilization 6) Depressurization of sterilization chamber (STEAM DISCHARGE) 7) Vacuum-drying phase 8) Load ventilation with sterile air 9) Bring the pressure to atmospheric level	The cycle is composed by 9 phases that are: 1) Preheating generator / chamber 2) Vacuum / Steam pulses 3) Temperature increase through pressure raise 4) Temperature and pressure stabilization 5) Sterilization 6) Depressurization of sterilization chamber (STEAM DISCHARGE) 7) Vacuum-drying phase 8) Load ventilation with sterile air 9) Bring the pressure to atmospheric level	The cycle is composed by 9 phases that are: 1) Preheating generator / chamber 2) Vacuum / Steam pulses 3) Temperature increase through pressure raise 4) Temperature and pressure stabilization 5) Sterilization 6) Depressurization of sterilization chamber (STEAM DISCHARGE) 7) Vacuum-drying phase 8) Load ventilation with sterile air 9) Bring the pressure to atmospheric level	Same

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Available cycles	<p>FUTURA</p> <ul style="list-style-type: none"> • (C1) 134°C universal – 2.1 bar – 4 min cycle – 61 min total cycle • (C2) 121°C universal – 1.1 bar – 20 min cycle - 73 min total cycle • (C4) 134°C solid wrapped – 2.1 bar – 4 min cycle – 46 min total cycle • (C5) 134°C Hollow unwrapped – 2.1 bar – 4 min - 50 min total cycle • User Configurable <p>CLASSIC</p> <ul style="list-style-type: none"> • (C1) 134°C universal – 2.1 bar – 4 min cycle – 61 min total cycle • (C2) 121°C universal – 1.1 bar – 20 min cycle – 73 min total cycle • (C4) 134°C solid wrapped – 2.1 bar – 4 min cycle – 46 min total cycle • (C5) 134°C Hollow unwrapped – 2.1 bar – 4 min – 50 min total cycle • User Configurable 	<p>FUTURA</p> <ul style="list-style-type: none"> • (C1) 134°C universal – 2.1 bar – 4 min cycle – 61 min total cycle • (C2) 121°C universal – 1.1 bar – 20 min cycle - 73 min total cycle • (C4) 134°C solid wrapped – 2.1 bar – 4 min cycle – 46 min total cycle • (C5) 134°C Hollow unwrapped – 2.1 bar – 4 min - 50 min total cycle • User Configurable <p>CLASSIC</p> <ul style="list-style-type: none"> • (C1) 134°C universal – 2.1 bar – 4 min cycle – 61 min total cycle • (C2) 121°C universal – 1.1 bar – 20 min cycle – 73 min total cycle • (C4) 134°C solid wrapped – 2.1 bar – 4 min cycle – 46 min total cycle • (C5) 134°C Hollow unwrapped – 2.1 bar – 4 min – 50 min total cycle • User Configurable 	<p>FUTURA</p> <ul style="list-style-type: none"> • (C1) 134°C universal – 2.1 bar – 4 min cycle – 61 min total cycle • (C2) 121°C universal – 1.1 bar – 20 min cycle - 73 min total cycle • (C4) 134°C solid wrapped – 2.1 bar – 4 min cycle – 46 min total cycle • (C5) 134°C Hollow unwrapped – 2.1 bar – 4 min - 50 min total cycle • User Configurable <p>CLASSIC</p> <ul style="list-style-type: none"> • (C1) 134°C universal – 2.1 bar – 4 min cycle – 61 min total cycle • (C2) 121°C universal – 1.1 bar – 20 min cycle – 73 min total cycle • (C4) 134°C solid wrapped – 2.1 bar – 4 min cycle – 46 min total cycle • (C5) 134°C Hollow unwrapped – 2.1 bar – 4 min – 50 min total cycle • User Configurable 	Same
Sterilizable loads (materials / devices)	- unwrapped metal or polymer instruments, dental handpieces, porous and fabric textiles - single and double package metal or polymer instruments, dental handpieces, porous and fabric textiles	- unwrapped metal or polymer instruments, dental handpieces, porous and fabric textiles - single and double package metal or polymer instruments, dental handpieces, porous and fabric textiles	- unwrapped metal or polymer instruments, dental handpieces, porous and fabric textiles - single and double package metal or polymer instruments, dental handpieces, porous and fabric textiles	Same
Sterilization of liquids & pharmaceuticals	NO	NO	NO	Same
Test Programs	Vacuum Test Helix / Bowie & Dick Test Vacuum Test + Helix / Bowie & Dick Test	Vacuum Test Helix / Bowie & Dick Test Vacuum Test + Helix / Bowie & Dick Test	Vacuum Test Helix / Bowie & Dick Test Vacuum Test + Helix / Bowie & Dick Test	Same
Sterilization cycle specifications				
Pre vacuum	Yes (single and fractionated) All cycles are pre- vacuum sterilization cycles	Yes (single and fractionated) All cycles are pre- vacuum sterilization cycles	Yes (single and fractionated) All cycles are pre- vacuum sterilization cycles	Same
Vacuum drying	Yes	Yes	Yes	Same
Sterilization temperature	273 °F or 250 °F (134 °C or 121 °C)	273 °F or 250 °F (134 °C or 121 °C)	273 °F or 250 °F (134 °C or 121 °C)	Same
Pressure	2.1bar/31.5psi or 1.1bar/17psi	2.1bar/31.5psi or 1.1bar/17psi	2.1bar/31.5psi or 1.1bar/17psi	Same

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Sterilization time	4 min (at 273°F) or 20 min (at 250°F)	4 min (at 273°F) or 20 min (at 250°F)	4 min (at 273°F) or 20 min (at 250°F)	Same
Single/double wrapped max load. kg / lbs	<p>4 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33kg per tray)</p> <p>2 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray)</p> <p>1 kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>0.6 kg unwrapped porous and fabric textiles</p> <p>0.5 kg single package porous and fabric textiles</p> <p>0.4 kg double package porous and fabric textiles</p> <p>Max N°9 handpieces</p> <p>Max 6 single sided lumen 118 mm x 0,8 or 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .</p>	<p>4.5 kg unwrapped metal or polymer instruments and dental handpieces (max 1.33kg per tray)</p> <p>2.25 kg single package metal or polymer instruments and dental handpieces (max 1.33 kg per tray)</p> <p>1.25 kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>0.75 kg unwrapped porous and fabric textiles</p> <p>0.6 kg single package porous and fabric textiles</p> <p>0.5 kg double package porous and fabric textiles</p> <p>Max N°9 handpieces</p> <p>Max 6 single sided lumen 118 mm x 0,8 or 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .</p>	<p>5 kg unwrapped metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>2.5kg single package metal or polymer instruments and dental handpieces (max 0.9 kg per tray)</p> <p>1.5kg double package metal or polymer instruments and dental handpieces (max 0.9kg per tray)</p> <p>1 kg unwrapped porous and fabric textiles</p> <p>0.75 kg single package porous and fabric textiles</p> <p>0.6kg double package porous and fabric textiles</p> <p>Max N°9 handpieces</p> <p>Max 6 single sided lumen 118 mm x 0,8 or 6 double sided lumened devices no longer than 115 mm and no smaller than 10 mm .</p>	Equivalent
Indicator Gauges	<p>During the cycle the following parameters are displayed on control panel:</p> <ul style="list-style-type: none"> - Temperature - Pressure - Process time 	<p>During the cycle the following parameters are displayed on control panel:</p> <ul style="list-style-type: none"> - Temperature - Pressure - Process time 	<p>During the cycle the following parameters are displayed on control panel:</p> <ul style="list-style-type: none"> • Temperature • Pressure • Process time 	Same
Printouts	<p>A printout / report with all the information about the cycle and sterilization result (POSITIVE / NEGATIVE) is available at the end of each cycle. The report is available in pdf file format (downloadable via USB key) or could be printed by the optional external printer.</p>	<p>A printout / report with all the information about the cycle and sterilization result (POSITIVE / NEGATIVE) is available at the end of each cycle. The report is available in pdf file format (downloadable via USB key) or could be printed by the optional external printer.</p>	<p>A printout / report with all the information about the cycle and sterilization result (POSITIVE / NEGATIVE) is available at the end of each cycle. The report is available in pdf file format (downloadable via USB key) or could be printed by the optional external printer.</p>	Same

Features	Subject Device		Predicate Device (K151597)	Substantially Equivalent
	B FUTURA-17 B CLASSIC-17	B FUTURA-22 B CLASSIC-22	B FUTURA-28 B CLASSIC-28	
Recorders	The cycle report can be printed with the optional printer. Otherwise it can be downloaded through Ethernet or wi-fi connection (only for FUTURA) or through an USB pen (both for FUTURA and CLASSIC)	The cycle report can be printed with the optional printer. Otherwise it can be downloaded through Ethernet or wi-fi connection (only for FUTURA) or through an USB pen (both for FUTURA and CLASSIC)	The cycle report can be printed with the optional printer. Otherwise it can be downloaded through Ethernet or wi-fi connection (only for FUTURA) or through an USB pen (both for FUTURA and CLASSIC)	Same

2.6.Performance Data

The design and sterilization process have been validated according to the requirements of AAMI ST55:2010. Especially the performed tests include Biological tests that show that the sterilization cycles are able to kill biological indicators assuring a sterility assurance level (SAL) of 10⁻⁶ reduction.

The results of the tests performed are summarized below:

- The chamber temperature during sterilization has been verified according to AAMI ST55 (points 4.4.3 / 5.4.3) using worst case loads . Chamber temperatures are always between -0°C and +3°C of the sterilization temperature set point during sterilization holding time.The results are in compliance with the acceptance criteria defined.
- The biological performances with a textile PCD have been verified according to AAMI ST55 (point 5.5.2). All the biological indicators of each cycle tested resulted sterile, ensuring a SAL of 10⁻⁶.
- The biological performances with wrapped instruments and lumen devices (double package) have been verified according to AAMI ST55 (point 5.5.4). All the biological indicators of each cycle tested resulted sterile, ensuring a SAL of 10⁻⁶.
- The biological performances with dental handpieces (double package) have been verified according to AAMI ST55 (point 5.5.5). All the biological indicators of each cycle tested resulted sterile, ensuring a SAL of 10⁻⁶.
- The Bowie Dick Test cycle has been verified using a FDA cleared Bowie-Dick test pack according to AAMI ST55 (point 5.6.1.1). After the test run, the Bowie-Dick test indicator showed a uniform color change.
- The Air Leak test has been performed according to AAMI ST55 (point 5.6.2). After the test run, the average leak rate is < 1mmHg (0.13kPa) which is in compliance with the acceptance criteria defined.

- The moisture retention test has been performed according to AAMI ST55 (points 5.7.1 / 5.7.2). Due to the different drying time the test has been conducted separately on B Classic-17, B Classic-22, B Futura-17 and B Futura-22 models, using worst case loads and wraps. The results are in compliance with the acceptance criteria defined by ANSI / AAMI ST55 for all the cycles tested.
- Software validation has been performed according to IEC 62304 First Edition 2006-05.
- Safety tests have been performed according to the following standards demonstrating the conformity of the subject device:
 - IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
 - IEC 61010-2-040 Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- Electromagnetic compatibility tests have been performed according to the following standards demonstrating the conformity of the subject device:
 - IEC 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

2.7. Conclusions

In conclusion, the subject Family of Steam Sterilizers B17 B22 series is substantially equivalent to predicate device K151597. Based on the intended use, technological characteristics, and performance data, the subject device is substantially equivalent and is as safe and as effective as the legally marketed predicate device.