July 8, 2019

Tuttnauer Ltd.
℅ Theodore Sullivan
Official Correspondent
Quarles & Brady
1701 K Street
Washington, District of Columbia 20006

Re: K181456
Trade/Device Name: Tuttnauer Horizontal Models:4472,5596,6690,66120,69120 and 69180 autoclaves
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: June 6, 2019
Received: June 7, 2019

Dear Theodore Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K181456

Device Name

Tuttnauer Horizontal Models: 4472, 5596, 6690, 6990, 66120, 69120 and 69180 autoclaves

Indications for Use *(Describe)*

The Tuttnauer Horizontal Models: 4472, 5596, 6690, 6990, 66120, 69120 and 69180 autoclaves that are intended for use by a health care providers to sterilize medical products by means of pressurized steam. The devices are autoclaves are intended to provide sterilization of heat stable medical devices; wrapped solids, hollow and porous products.

The standard cycles preprogrammed for the sterilizers are below.

Model **4472** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 23 kg
Wrapped	132C	4 minutes	20 minutes	Textile -11.1 kg Wrapped Tools - 23 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 23 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -11.1 kg Wrapped Tools - 23 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

Model **5596** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 23 kg
Wrapped	132C	4 minutes	20 minutes	Textile -22.2 kg Wrapped Tools - 23 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 23 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -22.2 kg Wrapped Tools - 23 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

Model **6690** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 46 kg
Wrapped	132C	4 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 46 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 46 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 46 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

Model **6990** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 46 kg
Wrapped	132C	4 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 46 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 46 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 46 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

Model **66120** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 69 kg
Wrapped	132C	4 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 69 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 69 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 69 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

Model **69120** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 69 kg
Wrapped	132C	4 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 69 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 69 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -33.3 kg Wrapped Tools - 69 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

Model **69180** - All door configurations				
Cycle name	Sterilization temperature	Sterilization Time	Dry Time	Maximum Load
IUSS	132C	3 minutes	1 minute	Tools - 92 kg
Wrapped	132C	4 minutes	20 minutes	Textile -44.4 kg Wrapped Tools - 92 kg
IUSS delicate	121C	30 minutes	1 minute	Tools - 92 kg
Wrapped delicate	121C	30 minutes	20 minutes	Textile -44.4 kg Wrapped Tools - 92 kg
Bowie and Dick	134C	3.5 minutes	2 minutes	N.A
Vacuum test	N.A	N.A	N.A	N.A

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."