



Food and Drug Administration
10903 New Hampshire Avenue
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April 29, 2016

Tanses Technologies Inc.
Mr. Kirk Kiremitci
President
4450 Highway 13
Fabreville, H7R 6E9 CA

Re: K152412

Trade/Device Name: T-32;T-40;T-44;T-52;T-72;TT-50
Regulation Number: 21 CFR 878.4635
Regulation Name: Ultraviolet Lamp For Tanning
Regulatory Class: Class II
Product Code: LEJ
Dated: August 17, 2015
Received: August 26, 2015

Dear Mr. Kirk Kiremitci:

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" (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.

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 yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152412

Device Name

T-Series Tanning beds and booths

Indications for Use (Describe)

The intended use of the T-Series tanning beds and booth is solely for the tanning of the human skin.

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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510(k) Summary

Date Prepared: August 28, 2015

Company name: Tanses Technologies inc.

Address: 4450 Highway 13
Laval, Quebec
H7R 6E9
Canada

Telephone number: 450-622-4004

Fax number: 450-622-1540

Contact name: Kirk Kiremitci

e-mail: kirk@tanses.com

Device trade name: Tanses Tanning beds and booth

Device model names: T32, T40, T44, T52,T72, TT50

Common/Usual name: Tanning bed and booth

Classification name: Sunlamp product

Classification code: LEJ

Device Classification: II

Regulation number: 21 CFR Part 878.4635

Predicate device

The T-Series tanning beds and booth listed in this 510(k) were all existing models, available for purchase in the US as legally marketed, class I, medical devices, 510k exempt, prior to September 2, 2014 and has been in the market since 1992 without any harm to any user.

As stated in the Final Reclassification Order published on June 2, 2014 in the Federal Register Vol. 79, No. 105, Page 31212 " **Any 510(k)-exempt sunlamp product or UV lamp intended for use in a sunlamp product legally offered for sale on or before September 2, 2014, can serve as a predicate for substantial equivalence purposes.**" We Tanses Technologies inc. would like to claim substantial equivalence to these legally marketed devices for this 510(k).

There have been no changes in either intended use or technological characteristics between the predicate devices and the devices named in this 510(k) since the September 2, 2014 cut-off date. As a result, the devices named in this 510(k) are as safe, as effective, and performs as well as the predicate devices.

Intended Use

The intended use for the T-Series tanning beds and booth is solely for the tanning of the human skin.

Description of the Devices

The T-Series tanning beds and booth are devices that omit ultraviolet radiation in the UVA and UVB range to produce a cosmetic tan. The T-Series family of units is made up of five (5) lay-down beds and one (1) stand-up unit.

All the lay-down beds in the T-Series are similar in design. They are made up of 3 sections, a canopy or top section (tans the front side of the user), a base or bed section (tans the back side of the user) and a side console (made up of cooling fans and controls). The beds are all 87" long and vary in width from 35 inches to 59 inches. The main difference in the bed design between the five (5) models is the amount of ultraviolet sunlamps they are equipped with.

The T-32 is equipped with 32 ultraviolet sunlamps.
The T-40 is equipped with 40 ultraviolet sunlamps.
The T-44 is equipped with 44 ultraviolet sunlamps.
The T-52 is equipped with 52 ultraviolet sunlamps.
The T-72 is equipped with 64 ultraviolet sunlamps.

The laydown beds are also designed to be equipped with optional face bulbs. The face bulbs are installed in the canopy section. Each unit can be outfitted with up to 3 face bulbs.

The lay-down beds are constructed of the same materials. Their frames are made up of power coated steel, stainless steel and anodized aluminum. All the beds are equipped with an acrylic sheet in both the base and canopy sections. The acrylic sheet is designed specifically for the transmission of ultraviolet light in the UVA and

UVB range. The acrylic sheets also server as a barrier to protect the user from lamp breakage and for sanitary purposes.

Page 5.2

The lay-down beds also share the exact same electrical components which mainly consist of a choke type ballast, starter and fluorescent sunlamp. The choke ballast acts like a valve and limits the amount of power/wattage to the lamp. The starter is needed in the initial start-up of the lamp; it generates an inductive kick which provides the high voltage needed to start the lamp. The fluorescent sunlamp is made specifically for tanning equipment. It is a low pressure mercury vapor gas-discharge lamp that emits most of its energy in the UVA and UVB range between 260nm-400nm. The ballast, starter and fluorescent sunlamp used in our lay-down beds are available in 100 Watt, 160 Watt or 200 Watt configuration. The face bulbs are physically smaller than the fluorescent sunlamps and are made of a quartz glass. They also work with a ballast and starter system. The ballast, starter/ignitor and face bulb are 400 watts.

The T-series booth (TT-50) is designed for a vertical application. It has the same metal construction as in the lay-down beds and also outfitted with the same electrical components. The booth is made up of 7 sections.

One (1) floor platform which is made of stainless steel.
Five (5) vertical columns, each equipped with ten (10) fluorescent sunlamps
One (1) overhead section which consists of an 18 inch cooling fan and controls.

Each sunlamp column is equipped with a powder coated steel grid to prevent the user from contacting the lamps. There handles attached to the overhead section in which the user can hold on to while tanning. The handles are made of steel and chromes plated. Face tanners are not available for the stand-up booth.

Both our lay-down beds and stand-up unit are configured to work with a timer system to ensure than the users of the equipment do not overexpose themselves to the ultraviolet light. The T-Series tanning beds and booth require 220 volts AC.

Technological Characteristics

The Technological characteristics of the tanning beds and booth is this 510(k) are the exact same as those in the predicate devices.

Performance Testing, Data

Tanses tanning equipment models have been tested and found satisfactory to the following tests and standards.

- IEC 60601-1-2 3rd edition medical electrical equipment Elecromagnetic compatibility/EMI requirements
- CSA/NRTL Class 3872-85, 3872-05 electrical standards, ANSI-UL1431, UL 482, CAN/CSA-C22.2 No224 M89
- Photo biological Safety evaluation of Optical emissions by Optronics Labs and RPTL labs for spectral analysis and time schedules
- Timer testing

CONCLUSION

Tanses tanning equipment is substantially equivalent to its Class-I predicate models without changes.