DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2016

Tanses Technologies, Inc.
Mr. Kirk Kiremitci
President
4450 Highway 13
Laval, Quebec, Canada H7R 6E9

Re: K162022
Trade/Device Name: Collagentex Rx-1
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: NHN
Dated: November 25, 2016
Received: November 29, 2016

Dear Mr. 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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162022

Device Name

Collagentex RX-1

Indications for Use *(Describe)*

Collagentex RX-1 model is intended to emit light energy in the near infrared spectrum to provide non heating adjunctive use for temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

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.

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510(k) Summary

Date Prepared

August 1, 2016

Submitter Information

Tanses Technologies inc.
4450 Highway 13
Laval, Quebec
H7R 6E9
Canada
Tel: 450-622-4004
Fax number: 450-622-1540
Contact name: Kirk Kiremitci
Email: kirk@tanses.com

Device Information

Device Trade Name:	Collagentex
Device Model Name:	RX-1
Common /Usual Name:	Near Infrared Lamp
Regulation Name:	Lamp, non heating, for adjunctive use in pain relief
Regulatory Class:	Class II
Regulation Number:	21 CFR 890.5500
Product Code:	NHN
Panel:	Physical Medicine

Predicate Device

Submitter:	Bioptron AG, Switzerland
Manufacturer:	Bioptron AG, Switzerland
Trade Name:	Bioptron
Model:	Bioptron Pro Light Therapy system, Bioptron Compact III Light Therapy System
Product Code:	NHN
510(k):	K032216

Device Description

Collagentex RX-1 model is a stand alone device of a single quartz lamp, emitting polychromatic visible to near infrared light from 580nm to 1500nm, non-collimating, non pulsing in order to offer exposure to the user where directed at a distance of 8" and farther from the body, non topical light therapy in order to relieve minor pain temporarily. The unit can be mounted on a table top or rolled on a base with casters. Narrow band filter and acrylic shield are designed to eliminate any

emission of ultraviolet or wavelength shorter than 480nm wavelengths. The lamp

replacement life is 500hrs. The exposure dosage is controlled by a user set timer. Exposure area is set to receive 44.2miliWatt/sqcm or 2.6 Joule/minute of exposure at the minimum distance. The device runs on AC power of 120 Volt 60 Hz or 220 Volt 50 Hz by plugging to main power.

Intended Use

Collagentex RX-1 model is intended to emit light energy in the near infrared spectrum to provide non heating adjunctive use for temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

Technical Characteristics

Characteristics	Collagentex Rx-1	Bioptron Pro Light & Compact III
Light source	Quartz Lamp	Quartz Lamp
Light Source Power	500 W	90 W
Exposure area	23cm diameter (4.37 times larger)	11cm diameter
Emitted light wavelength (effective)	580nm to 1500nm	590nm to 1550nm
Emitted light polarization	Not polarized	Polarized >95%
Indications of use	temporary pain relief	temporary pain relief
Product code	NHN	NHN
Emitted light intensity	44.2 miliWatt/sqcm (2.6 Joule/minute)	40 miliWatt/sqcm (2.4 Joule/minute)
Power supply	120 VAC or 240 VAC	120 VAC or 240 VAC
Design Principle	Quartz halogen lamp with a filter	Quartz halogen lamp with a filter
Skin Surface Temperature	Under 42 C	Under 42 C
Treatment Time	20 minutes	20 minutes
Patient Contact	No contact to human body	No contact to human body
Biocompatibility	No contact to human body	No contact to human body
Electrical Safety	NRTL, CSA, ANSI	CE
Electromagnetic Compatibility	60601-2 (3rd ed.)	CE
Risk Analysis	According to ISO 13485/14971:2007	CE
Photobiological safety of the device	IESNA/ANSI RP-27.1-05	CE
Photobiological safety of eyewear	IESNA/ANSI RP-27.3-07	CE

From the comparison form above, the subject device and the predicate device have the same indications for use, operation principle, skin temperature, wavelength spectrum, irradiation intensity and treatment time.

Performance Data

The subject device has been tested and complied with the following voluntary recognizable standards IEC60601-1-2 3rd edition Electromagnetic compatibility requirements as well NRTL, CSA, ANSI electrical safety standards and ANSI/IESNA RP-27.1-05 and ANSI/IESNA RP-27.3-07 photobiological safety standards for the device and the eye protection.

According to the test result in this submission, the irradiation distance is 20 cm and the irradiation time is 20 minutes and the skin temperature is less than 42 C degrees.

Conclusion

Collagentex RX-1 model is substantially equivalent to the predicate device in K032216.