



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 14, 2017

Chongqing Yuhe Medical Instruments Co., Ltd.
Liu Yong
General Manager
No.104-8 City Garden Mid Road,
Shapingba District
Chongqing, 400038 CN

Re: K162590
Trade/Device Name: Bashan TDP Heat Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: January 2, 2017
Received: January 9, 2017

Dear Liu Yong:

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162590

Device Name

Bashan TDP Heat Lamp

Indications for Use (Describe)

Bashan TDP Heat Lamp is used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

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.

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Sponsor: Chongqing YUHE Medical Instruments Co., Ltd.
Subject Device: Bashan TDP Heat Lamp, Models: TDP-124D, DP-166D, TDP-124F, TDP-166F
File No.: 510(k) Submission Report (V1.0), Chapter 5 - 510(k) Summary

Chapter 5. 510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Company Name: Chongqing YUHE Medical Instruments Co., Ltd.
Establishment registration number: Applying
Address: No.104-8 City Garden Mid Road, Shapingba District, Chongqing, China
Name of contact person: Liu Yong
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Application Correspondent:

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Guangzhou GLOMED Biological Technology Co., Ltd.
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Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information:

Type of 510(k) Submission: Traditional
Common Name: Infrared lamp
Trade Name: Bashan TDP Heat Lamp
Models: TDP-124D, TDP-166D, TDP-124F, TDP-166F
Classification Name: lamp, infrared, therapeutic heating
Review Panel: Physical Medicine
Product Code: ILY
Regulation Number: 21CFR890.5500
Regulation Class: 2

Sponsor: Chongqing YUHE Medical Instruments Co., Ltd.
Subject Device: Bashan TDP Heat Lamp, Models: TDP-124D, DP-166D, TDP-124F, TDP-166F
File No.: 510(k) Submission Report (V1.0), Chapter 5 - 510(k) Summary

3. Predicate Device Information:

Predicate Device 1:

510(K) Number: K081720

Company Name: Prime Herbs Corporation

Trade Name: Precision TDP Lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp, Wonder Lamp

Common Name: Infrared Heating Lamp

Product Code: ILY

Predicate Device 2:

510(K) Number: K043558

Company Name: Chongqing Xinfeng Medical Instrument Co., Ltd.

Trade Name: Xinfeng Lamp

Common Name: Infrared Heating Lamp

Product Code: ILY

4. Device Description

Bashan TDP Heat Lamp is used to provide topical heating to the body. It is specially engineered using a rare earth ceramic plate. Emission spectrum ranges from 5 to 25 microns, 110 volt power, 250 watts. It includes timer, safety fuses.

5. Intended Use / Indications for Use

Bashan TDP Heat Lamp is used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

6. Test Summary

Bashan TDP Heat Lamp is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- ◆ AAMI/ANSI ES60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance, Edition 2005/(R)2012 and A1:2012;
- ◆ IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, Edition 4.0, 2014;

Sponsor: Chongqing YUHE Medical Instruments Co., Ltd.
Subject Device: Bashan TDP Heat Lamp, Models: TDP-124D, DP-166D, TDP-124F, TDP-166F
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- ♦ IEC 60601-1-11: Medical Electrical Equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment, Edition 2.0, 2015;
- ♦ The performance test report has also been conducted to verify the output parameters of the device.

The result of tests indicates that the Bashan TDP Heat Lamp is safe and effective, and the substantial equivalent performance as the legally marketed predicate device.

7. Usability Study

Usability study was conducted on 500 eligible device users. The study evaluated the users' ability to comprehend the device labeling and operate the device as intended in a safe and effective means. The study results showed that potential device users could successfully operate the device as intended with no safety issues reported.

8. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Predicate Device		Remark
Manufacturer	Chongqing YUHE Medical Instruments Co., Ltd.	Prime Herbs Corporation	Chongqing Xinfeng Medical Instrument Co., Ltd.	--
Device Name	Bashan TDP Heat Lamp (Models: TDP-124D, TDP-166D, TDP-124F, TDP-166F)	Precision TDP Lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp, Wonder Lamp	Xinfeng Heating Lamp (Models: CQ-27, CQ-36)	--
510(k) Number	Applying	K081720	K043558	--
Product Code	ILY	ILY	ILY	SE
Indications for Use	Bashan TDP Heat Lamp is used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor	The Precision TDP lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp and Wonder Lamp may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary	Bashan TDP Heat Lamp is used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles.	SE

Sponsor: Chongqing YUHE Medical Instruments Co., Ltd.
Subject Device: Bashan TDP Heat Lamp, Models: TDP-124D, DP-166D, TDP-124F, TDP-166F
File No.: 510(k) Submission Report (V1.0), Chapter 5 - 510(k) Summary

	sprains and strains, and minor muscular back pain.	increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.	
Type of Use	OTC	OTC	Prescription	SE
Key Components	Heating head Swing arm Control box Pedestal with extension	Heating head Swing arm Control box Pedestal with extension	Heating head Swing arm Control box Pedestal with extension	SE
Power Input Rating	250W maximum, 50/60 Hz	250W maximum, 50/60 Hz	250W maximum, 50/60 Hz	SE
Spectrum Range	5 ~ 25 microns	2 ~ 50 microns	5 ~ 25 microns	SE
Warming Up Time	15 minutes	--	15 minutes	SE
Total Working Hours	1000 Hours	1200 ~ 1500 Hours	1000 Hours	SE
Operating Timer	Up to 60 minutes	--	Up to 95 minutes	SE Note 1
Placement Type	Models TDP-124D & TDP-166D: desktop type; Models TDP-124F, TDP-166F: floor type	--	Desktop type	SE Note 2
Radiant Plate Diameter	TDP-124D & TDP-124F: 12.4 cm; TDP-166D & TDP-166F: 16.6 cm	--	16.6 cm	SE Note 3
Skin Temperature	The distance from lamp head and the testing result: (1) Models TDP-124D & TDP-124F: 20cm distance: 45°C; 25cm distance: 42°C; 30cm distance: 40°C (2) Models TDP-166D & TDP-166F: 20cm distance: 45°C; 25cm distance: 43°C; 30cm distance: 41°C	--	The distance from lamp head and the testing result: 8" (20cm) distance: 45°C; 10" (25cm) distance: 43°C; 12" (30cm) distance: 41°C	SE Note 4
Compliance Standards	AAMI/ANSI ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	SE Note 5

Sponsor: Chongqing YUHE Medical Instruments Co., Ltd.
Subject Device: Bashan TDP Heat Lamp, Models: TDP-124D, DP-166D, TDP-124F, TDP-166F
File No.: 510(k) Submission Report (V1.0), Chapter 5 - 510(k) Summary

Comparison in Detail

Note 1 - 3:

The Operating Timer, Placement Type, Inner Cover Diameter of subject devices are a little difference from predicate devices. They are both compliance with IEC 60601-1 requirements. So the difference will not raise any safety or effectiveness issue.

Note 4:

The Skin Temperature of subject devices are a little difference from predicate devices, but the effective skin temperatures are between 40 ~ 45 °C in 8" ~ 12" distance from lamp head. So the difference will not raise any safety or effectiveness issue.

Note 5:

The Compliance Standards of subject devices are a little difference from predicate devices, but the subject devices are also complied with home healthcare environment used device standard IEC 60601-1-11 for OTC used. So the difference will not raise any safety or effectiveness issue.

Final conclusion:

The subject device Bashan TDP Heat Lamp (Models: TDP-124D, TDP-166D, TDP-124F, TDP-166F) has all features of predicate devices, the Precision TDP Lamp, Precision Heat Lamp, Precision Infrared Lamp, Marvel Lamp, Wonder Lamp (K081720) and Xinfeng Heating Lamp (K043558). The differences between them do not affect the safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate devices.

9. Date of the summary prepared: February 9, 2017