K111341

FEB 29 2012

510(k) Summary

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

Date: 02/28/2012

1. Company making the submission

	Submitter
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2. U.S Agent/Contact Person

LK Consulting Group
951 Starbuck St. Unit J, Fullerton, CA 92833
Priscilla Chung
Phone: 714-869-3080 Fax: 714-409-3357
Email: info@LKconsultinggroup.com

3. Device

Trade Name: CLEANE / CLEANE POP
Common Name: Acne Treatment Device
Classification: Class II
Classification regulation: 21 CFR890.5740
Product Code: OZC

4. Predicate Device:

Zeno by Tyrell, Inc. (K043377)

5. Description:

The CLEANE and the CLEANE POP are potable had-held devices that produce accurately controlled low level sustained heat for use in treating mild to moderate acne. The devices are designed to treat individual acne blemishes for 2 1/2 minutes at

a preset temperature. The treatment tip is made from a biocompatible material and delivers the specific low-level heat to the individual acne blemish.

6. Indication for use:

CLEANE and CLEANE POP are indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

7. Performance Data

Biocompatibility testing of the tip material was conducted in accordance with ISO 10993 Biological Testing of Medical and the tip material is considered biocompatible.

CLEANE and CLEANE POP were tested for EMI in accordance with the IEC 60601. They operate within the EMI emission, susceptibility and static discharge levels specified in the IEC 60601 standard.

Self selection study and labeling comprehension study were conducted to ensure usability of lay users. The performance data supplied in this 510K demonstrated that the majority of study participants were able to properly self-select themselves using the box labeling and were able to properly use the device by reading the instructions for use without any assistance.

8. Basis for Substantial Equivalence

Upon reviewing the safety and effectiveness information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the CLEANE and the CLEANE POP are determined by Medicon Co., Ltd. to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 29 2012

Medicon Co., Ltd.
% LK Consulting Group
Ms. Priscilla Chung
951 Starbuck Street, Unit J
Fullerton, California 92833

Re: K111341
Trade/Device Name: CLEANE / CLEANE POP
Regulation Number: 21 CFR 890.5740
Regulation Name: Powered heating pad
Regulatory Class: Class II
Product Code: OZC
Dated: February 01, 2012
Received: February 06, 2012

Dear Ms. Chung:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111341

Device Name: CLEANE / CLEANE POP

Indications for Use:

The CLEANE and the CLEANE POP are indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use ___
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _√__
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEE DED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111341