APR 18 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.
The Assigned 510(k) number is k113332

Submitter's Identification:
ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121
Tel.: 858-875-8057
Fax: 858-875-8099

Date Prepared: 4/11/2012

Contact Person:
Aaron Friday
RA/CA Associate

Proprietary Name of the Device:
On Call® Lancing Device

Common Name:
Lancing Device, blood lancet

Classification Name:
Class II 862.1345 Glucose test system

Predicate Device:
On Call® Plus Lancing Device under On Call® Plus Blood Glucose Monitoring System.
ACON Laboratories Inc., 10125 Mesa Rim Road, San Diego, CA 92121, USA
510(k) Number: K090057

Device Name:
On Call® Lancing Device

Proprietary Name	Classification	Product Code	Description	Common Name
On Call® Lancing Device	862.1345 Class II	NBW	Blood Lancet	Lancets

Description:
The On Call® Lancing Device is a mechanical device holding and firing the lancet for collecting capillary whole blood sampled from the fingertip, palm, and forearm in conjunction with On Call® Chosen Blood Glucose Monitoring System for testing glucose in blood.

Intended Use:
The On Call® Lancing Device is used with On Call® disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood. The On Call® Lancing Device is intended to be used by a single patient and should not be shared.

Technological Characteristics:

Specification of Lancing Device:

Features	Specification
Lancing Device Length	103mm
Diameter(1)	16mm
Diameter(2)	15.6mm
Plastic composition	ABS (Acrylonitrile-Butadiene-Styrene)
Clear Cap composition	Transparent ABS

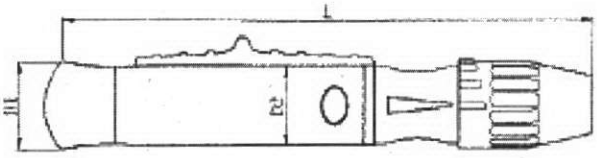
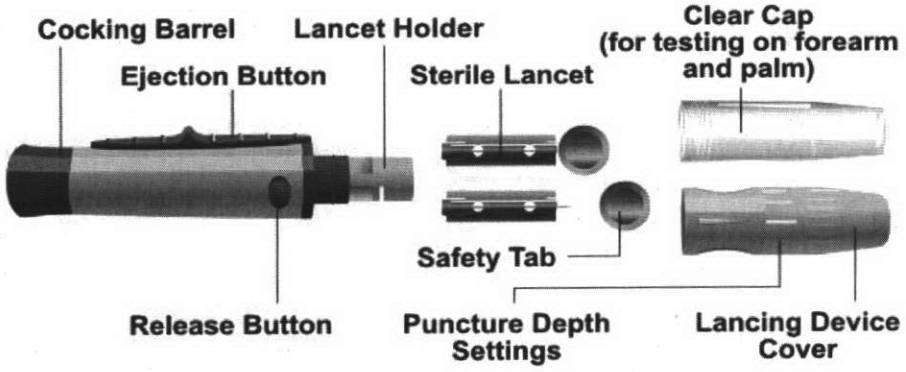


圖 1 STERILANCE 施柔采血筆（短款卸針型, 六幅）
Drawing 1 LDE STERILANCE Lancing devices

On Call® Lancing Device

The On Call® Lancing Device is for collecting fresh capillary blood samples obtained from the fingertip, forearm, and palm. The lancing device is manufactured for ACON Laboratories by EN ISO 13485-certified third-party supplier: Sterilance Medical (Suzhou) Inc. (No. 68 Litanghe Rd., Xiangcheng, Suzhou, Jiangsu 215113, P.R.China).



Comparison to Predicate Device:

Features	On Call® Lancing Device	On Call® Plus Lancing Device under On Call Plus Blood Glucose System (K090057)
Similarities		
Intend for Use	The On Call® Lancing Device is used with On Call® disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood. The On Call® Lancing Device is intended to be used by a single patient and should not be shared.	The On Call® Plus Lancing Device is used with compatible disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood.
Puncture device to obtain micro blood samples	**Yes**	**Yes**
Lancet retracted after use to prevent sharp injure	**Yes**	**Yes**
Clear cap for testing on forearm and palm	**Yes**	**Yes**
Mechanical loading and firing function	**Cocking barrel with releasing button**	**Same**
Differences		
Lancet no touch ejection function	**Yes**	**No**
Puncture Depth setting	**6 steps**	**5 steps**

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents:

The following guidance documents were followed:

1 "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

2 "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk or Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
3 US Environmental Protection Agency Office of Pesticide Programs. List D: EPA's Registered Antimicrobial Products Effective Against Human HIV-1 and Hepatitis B Virus (January 9, 2009) http://www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf
4 Letter to Manufacturers of Blood Glucose Monitoring Systems Listed With the FDA http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935. htm

Laboratory Testing Virucidal Efficacy Validation Testing:
Under the conditions of cleaning and disinfection protocol using proposed disinfectant wipe, all components listed above from the Lancing Device had demonstrate complete inactivation of duck Hepatitis B in surrogate to human Hepatitis B. It is demonstrated that the proposed disinfection protocol with the disinfectant is effective against Hepatitis B virus through viral challenge of the material used to manufacture the housing of the lancing device.

The detailed Virucidal Efficacy Validation Testing protocol and report are presented in Attachment I.

Discussion of Clinical Tests Performed:
On Call® lancing device is a class I device exempt.
On Call® Chosen Blood Glucose Monitoring system clinical tests report please refers to k111371.

Conclusion:
The laboratory testing for disinfection and the clinical study results of On Call® Lancing Device in conjunction with On Call® Chosen Blood Glucose Monitoring system (k111371) demonstrate that the On Call® Lancing Device is substantially equivalent to the On Call® Plus Lancing Device in the On Call® Plus Blood Glucose Monitoring System (k090057) and it is safe, effective and easy-to-use.

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

Acon Laboratories, Inc.
% Mr. Aaron Friday
Clinical & Regulatory Affairs Associate
10125 Mesa Rim Road
San Diego, California 92121

APR 18 2012

Re: K113332
Trade/Device Name: On Call® Lancing Device
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: FMK, NBW
Dated: March 2, 2012
Received: March 5, 2012

Dear Mr. Friday:

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: k113332

Device Name: On Call® Lancing Device

The On Call® Lancing Device is used with On Call® disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood. The On Call® Lancing Device is intended to be used by a single patient and should not be shared.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off
Office of Device Evaluation
Evaluation and Safety
510(k) k113332

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

510(k) Number K113332