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

May 12, 2016

Genteel, LLC
% Mr. Mark DuVal, J.D., FRAPS
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: K153670
Trade/Device Name: Genteel Lancing Device
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: Class I
Product Code: FMK
Dated: December 14, 2015
Received: December 31, 2015

Dear Mr. Mark DuVal:

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

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)*
K153670

Device Name
The Genteel Lancing Device

Indications for Use *(Describe)*

The Genteel lancing device is used with disposable sterile lancets to draw capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood.

The Genteel lancing device is for Single Patient Use Only.

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

1. Date Prepared: 2016-05-10

2. Submitted on behalf of:

Genteel, LLC
2904 Rawhide St
West Linn, OR 97068
Phone: (844) 436-8335 (844-GENTEEL)
Email: support@mygenteel.com

3. Contact person:

Mark DuVal, J.D., FRAPS
President & CEO, DuVal & Associates, P.A.
825 Nicollet Mall
Suite 1820
Minneapolis, MN 55402
Phone: (612) 338-7170
Email: duval@duvalfdalaw.com

4. Trade Name: Genteel
Common/Usual Name: Lancing device
Product Code: FMK (Blood lancet)
Classification Name: Manual surgical instrument for general use (21 CFR 878.4800, Product Code: FMK)

5. Predicate device:

510(K) Number:	K113332
Device Name:	On Call® Lancing Device
Applicant:	Acon Laboratories, Inc.
510(K) Number:	N/A - 510(k) exempt
Device Name:	Autolet® Impression Lancing Device (Manufactured by Owen Mumford Limited)
Applicant:	N/A - 510(k) exempt

6. Device Description:

The Genteel® Lancing Device (Genteel) is a dual-spring mechanical blood lancet holder for collecting capillary whole blood sampled from the fingertip or alternate sites. The Genteel lancing device is used with commercially available, sterile, standard square shaft blood lancets.

7. Intended Use:

   Genteel is a blood lancet holder. Its indications for use statement is as follows:

   The Genteel lancing device is used with disposable sterile lancets to draw capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood. The Genteel lancing device is for Single Patient Use Only.

8. Summary of Technological Characteristics of Genteel compared to predicate devices:

   The Genteel® Lancing Device (Genteel) is substantially equivalent to the chosen predicate devices, the On Call® Chosen Lancing Device (K113332) and the Autolet Impression Lancing Device (510(k) exempt). Genteel has the same intended use as the predicate devices, in that they are both for firing lancets for the collection of capillary blood samples. Genteel and the Autolet Impression predicate device are also intended for use for fingertip and alternate site testing. Genteel and the predicate devices are primarily made from different plastics which are both medical grade, and also have the same fundamental technological characteristics in that they use the same simple, well-known, dual-spring technology for firing square-shaft lancets. They also have varying puncture depth settings, via six interchangeable contact tips on Genteel and six and seven adjustable settings on adjustable dials on the predicate devices. There is a slight difference between Genteel and the predicate devices for aiding the drawing of blood after lancing. The predicate devices instruct users to massage the skin by the lancing site, whereas Genteel generates a soft vacuum to help draw blood to the surface after lancing. As demonstrated, Genteel is substantially equivalent to the predicate devices.

9. Non-Clinical Performance Data:

   Performance testing includes a Penetration Capability protocol that demonstrates substantial equivalence.

10. Clinical Performance Data:

    Not applicable. Genteel does not require clinical testing for demonstrating substantial equivalence and safety/efficacy.

11. Conclusions from Performance Testing:

    The Genteel 510(k) documents and results of the non-clinical testing demonstrate that Genteel is substantially equivalent to the On Call Chosen Lancing Device and the Autolet Impression Lancing Device.