



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

October 27, 2015

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

Statcorp Medical
Wayne Emmert
Director of Operations
14476 Duval Place West
Suite 303
Jacksonville, Florida 32218

Re: K152801

Trade/Device Name: Ultracheck Spacelabs ABP Cuff-child, Ultracheck Spacelabs ABP Cuff-small Adult, Ultracheck Spacelabs ABP Cuff-adult, Ultracheck Spacelabs ABP Cuff-large Adult

Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: September 25, 2015
Received: September 28, 2015

Dear Wayne Emmert:

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,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152801

Device Name

Statcorp Medical UltraCheck Spacelabs ABP Cuffs

Indications for Use (Describe)

Statcorp Medical UltraCheck® Spacelabs ABP Cuffs are used with identified devices intended for the non-invasive measurement of pediatric and adult human blood pressure.

Statcorp Medical UltraCheck® Spacelabs ABP Cuffs are intended for use by or under the supervision of qualified medical personnel.

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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**UltraCheck® Spacelabs ABP Blood Pressure Cuffs
510(k) Summary of Safety and Effectiveness**

I. Applicant Information

- A. Applicant Information: Statcorp Medical
14476 Duval Place West, Suite 303
Jacksonville, FL 32218
1-904-786-5113
- B. Official Contact: Wayne Emmert
Director of Operations
- C. Date of Summary: 9/25/15

II. Device Information

- A. Proprietary Name : UltraCheck® Spacelabs ABP Cuffs
- B. Common Names: Blood Pressure Cuff
- C. Classification Device Name: Blood Pressure Cuff
- D. Classification Regulatory Description: Blood Pressure Cuff
- E. Product Code: DXQ
- F. Regulatory Class: II
- G. Panel: Cardiovascular

III. Predicate Device

The predicate devices for these cuffs are the Ultracuff Blood Pressure Cuffs (for Spacelabs ABP), 510(k) # K954282.

IV. General Description

The Statcorp UltraCheck® Spacelabs ABP cuffs in this 510(k), are applied to a patient limb and connected pneumatically to an oscillometric blood pressure monitor to enable non-invasive blood pressure measurements. The cuff is made of flexible polymeric material, a section of which forms an integrated inflatable bladder. The cuffs in this 510(k) are secured by looping the cuff through an attached oblong ring back onto itself to enable easier self-application. These cuffs are connected pneumatically through a one piece tube to the Spacelabs ABP Monitor.

V. Indications

The Statcorp UltraCheck® Spacelabs ABP Cuffs are used with identified devices intended for the non-invasive measurement of pediatric and adult human blood pressure.

UltraCheck® Blood Pressure Cuffs are intended for use by or under the supervision of qualified medical personnel.

VI. Comparison to Predicate

The UltraCheck® Spacelabs ABP cuffs in this 510(k) are similar to the Statcorp Ultracuff described in K954282 in that use the same cuff materials, bladder sizes and methods of construction. It differs from the fact that these cuffs are designed to be applied by passing the extended portion through a ring and attaching the cuff back onto itself. The predicate device is merely wrapped around the arm in the same direction. There is also an added fringe on the weld side of the cuff which eases the transition from the stiffer portion of the weld to the edge of the cuff which is added to provide for patient comfort.

VII. Test Summary

Mechanical tests included

- Pressure cycle testing to 10,000 cycles and application testing to 1,000 cycles to validate life.
- Mechanical stress testing to validate ring durability
- Cleaning validation tests to validate cleaning recommendations
- Label integrity testing to validate label chemical resistance and legibility

Clinical Accuracy testing performed per the methodology and requirements of AAMI ANSI ISO 81060-2 (2013)

VIII. Conclusions

Based upon the above test results the Statcorp Medical UltraCheck® Spacelabs ABP Cuffs are substantially equivalent to the predicate devices cited and safe and effective for their stated intended use.