K122365

Statcorp Medical

# UltraCheck® Curve 510(k) Summary

JUN 04 2013

## I. Applicant Information

A. Applicant Information: Statcorp Medical
14476 Duval Place West, Suite 303
Jacksonville, FL 32218
1-904-861-2347

B. Official Contact: Wayne Emmert
Director of Operations

C. Date of Summary: 1/30/13

## II. Device Information

A. Proprietary Name : UltraCheck® Curve Blood Pressure cuff

B. Common Names: Blood Pressure Cuff

C. Classification Device Name: Antimicrobial Blood Pressure Cuff

D. Classification Regulatory Description: Blood Pressure cuff

E. Product Code: OED

F. Regulatory Class: II

G. Panel: Cardiovascular

## III. Predicate Device

The predicate devices for this cuff are the Philips Series of Multi-Patient Cuffs and Single-Patient Cuffs, 510(k) # K071885 and the Ultracuff Blood Pressure Cuff, 510(k) # K954282.

## IV. General Description

The UltraCheck® Blood Pressure cuffs including the UltraCheck® Curve Cuffs in this 510(k), are applied to a patient limb and can be connected pneumatically to manual or oscillometric manometers to enable non-invasive blood pressure measurements. While the general shape of the other cuffs in the UltraCheck® product line is rectangular, the UltraCheck® Curve Cuffs in this 510(k) are conical in shape. They are made of flexible polymeric material a section of which forms an integrated inflatable bladder. A hook and loop closure system on each cuff may be used to secure the cuff around the patients limb. The cuff is connected pneumatically through a one piece lumen to a Patient Monitor or Sphygmomanometer.

## V. Indications

The UltraCheck® Curve Blood Pressure Cuffs are used with identified devices intended for the non-invasive measurement of 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 table below indicates the similarities and differences between the UltraCheck® Curve and the predicate devices.

| | New UltraCheck® Curve Cuffs | UltraCheck® Cuffs in K954282 | Philips K071885 | Philips K071885 |
|---|---|---|---|---|
| Models | Adult Bariatric BRUS3854 BRUD3854 | Adult Large US3544 & UD3544 | Adult Large M4557B | Adult X-Large for Thigh M4559B |
| Intended use- as listed in 510(k) which may include other cuff sizes in the case of the predicates.. | "cuffs are to be used with identified devices intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of adult human | cuffs are to be used with identified devices intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of infant, | "cuffs are to be used with identified devices intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of infant, | cuffs are to be used with identified devices intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of infant, |

| | | | | |
|---|---|---|---|---|
| | blood pressure | pediatric and adult human blood pressure.. | pediatric and adult human blood pressure." | pediatric and adult human blood pressure." |
| Base Cuff Material | Nylon Fabric w/polyurethane backing | Nylon Fabric w/polyurethane backing | Nylon with polyurethane backing | Nylon with polyurethane backing |
| Antimicrobial Additive | Micropel - same as Phillips Predicate | None | Micropel | Micropel |
| Tube Material | Dynaflex G2709-100-00 | Dynaflex G2709-100-00 | Black unknown | Black unknown |
| Number of adapter tubes | BRUS3854-single BRUD3854-dual | US3544-single UD3544-Dual | Option of either 1 or 2 with adapter | Option of either 1 or 2 with adapter |
| Sizes and Dimensions | 38cm to 54 cm | 35cm to 44cm | 35cm to 44cm | 42cm to 54cm |
| Shape | Conical | Rectangular | Rectangular | Rectangular |
| Method of attachment | Velcro | Velcro | Velcro | Velcro |
| Storage/Ambient Temperature Range: | 20C to 55C | 20C to 55C | Unknown | Unknown |
| Compatible Monitors | Welch Allen<br>Draeger<br>Colin<br>Datascope<br>Spacelabs<br>Mindray<br>Siemens<br>GE (Marquette)<br>Datex/Ohmeda<br>Criticon<br>Criticare<br>Phillips<br>Zoll<br>CAS<br>Physio<br>Invivo<br>Physiogard | Welch Allen<br>Draeger<br>Colin<br>Datascope<br>Spacelabs<br>Mindray<br>Siemens<br>GE (Marquette)<br>Datex/Ohmeda<br>Criticon<br>Criticare<br>Phillips<br>Zoll<br>CAS<br>Physio<br>Invivo<br>Physiogard | Welch Allen<br>Draeger<br>Colin<br>Datascope<br>Spacelabs<br>Mindray<br>Siemens<br>GE (Marquette)<br>Datex/Ohmeda<br>Criticon<br>Phillips | Welch Allen<br>Draeger<br>Colin<br>Datascope<br>Spacelabs<br>Mindray<br>Siemens<br>GE (Marquette)<br>Datex/Ohmeda<br>Criticon<br>Phillips |

## VII. Test Summary

Testing was performed to show compliance with the following standards and guidance documents.

- AAMI/ANSI SP10 2002, Am1: 2003: Manual, electronic, or automated sphygmomanometers.
- ISO 10993-1 2009 Biological evaluation of medical devices
- FDA guidance on Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents "

This testing included:

A clinical accuracy study showing the accuracy of the cuff is unchanged from the predicate device when used with the manual or electronic sphygmomanometer and the results compared to the measurements collected using the predicate cuffs.

A biocompatibility study of the material per ISO 10993-1 which indicated no biocompatibility issues.

A shelf life study indicating the cuffs performance did not degrade over a three year shelf life.

A textile test performed per Mil Std 810E 508.4 which indicated the antimicrobial agent inhibited fungal growth in the cuff material.

## VIII. Conclusions

Based upon the above test results the UltraCheck® Curve Blood Pressure Cuffs are substantially equivalent to the predicate devices cited and safe and effective for their stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 4, 2013

Statcorp Medical
c/o Mr. Wayne Emmert
Director of Operations
14476 Duval Place West, Suite 303
Jacksonville, FL 32218

Re: K122365
Trade/Device Name: UltraCheck Curve Blood Pressure Cuffs
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: OED
Dated: May 1, 2013
Received: May 2, 2013

Dear Mr. 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 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,

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): | K122365 |
| Device Name: | UltraCheck® Blood Pressure Cuff |
| Indications for Use: | UltraCheck® Curve Blood Pressure Cuffs are used with identified devices intended for the non-invasive measurement of adult human blood pressure.<br>UltraCheck® Blood Pressure Cuffs are intended for use by or under the supervision of qualified medical personnel. |

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
2013.06.04 16:11:07 -04'00'