



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Zefon International  
c/o Mr. Scott Ryan  
President  
5350 SW 1<sup>st</sup> Lane  
Ocala, Florida 34474

DEC 19 2008

Re: K082630

Trade/Device Name: Zefon VitalCheck Blood Pressure Cuff, NIBP Tubing and Adapters  
Regulation Number: 21 CFR 870.1120  
Regulation Name: Blood Pressure Cuff  
Regulatory Class: Class II (Two)  
Product Code: DXQ  
Dated: December 4, 2008  
Received: December 5, 2008

Dear Mr. Ryan:

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.

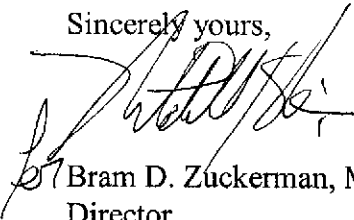
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

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807); labeling (21 CFR Part 801); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure



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Air Sampling Equipment  
Medical Products  
Injection Molding

### Indications for Use

510(k) Number (if known): K082630

Device Name: Zefon VitalCheck Blood Pressure Cuff, NIBP Tubing & Adapters

Indications For Use: Zefon NIBP blood pressure cuffs, tubing & adapters are reusable accessories used in conjunction with non-invasive automatic blood pressure monitors or non-invasive manual blood pressure measurement systems.

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

*[Signature]*  
for BZuckerman  
(Division Sign-Off) 12/18/08  
Division of Cardiovascular Devices

510(k) Number K082630

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

