

APR 22 2005

March 18, 2005

510(k) Summary - *safePICO*

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Submitter: Radiometer Medical ApS
Address: Åkandevvej 21, DK-2700 Brønshøj, Denmark
Phone: +45 3827 3827 or +45 3827 3390 (direct)
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Contact Person: Ms. Kirsten Rønø
Date Summary Prepared: March 18, 2005

Trade Name: *safePICO*
Common name: Vented Arterial Blood Sampler
Classification Name: Piston Syringe

Predicate Devices

PICO Arterial Blood Sampler (K962158) and PRO-VENT with NEEDLE-PRO (K011925).

Device Description

The barrel and plunger of the *safePICO* Arterial Blood Sampler is identical to the PICO70 Arterial Blood Sampler marketed by Radiometer Medical ApS and cleared under K962158, PICO Arterial Blood Sampler.

New features

In the sampler barrel the *safePICO* includes a soft magnetic steel ball for mixing the sample before measurement. On the outside of the barrel, the *safePICO* sampler has a barcode that is unique for each sampler, thus allowing independent identification of each sampler.

The *safePICO* sampler is delivered with a new vented tip cap that allows the sampler to be vented after the appliance of the tip cap to the male connector of the sampler. Further, the *safePICO* may be delivered either with a conventional needle cube of PVC or with a new needle shield device connected to the needle in order to avoid accidental needle stick of a user.

Use of the steel ball, the unique barcode and the vented tip cap is particularly relevant when using the *safePICO* sampler in a new automatic inlet module (FLEXQ) of the ABL800 FLEX analyzer (subject of a separate 510(k) application). In the new inlet module, the barcode may be automatically read and the steel ball is used to automatically mix the sample prior to an automatic transfer of the sample to the ABL800 FLEX analyzer via the vented tip cap.

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The safePICO sample is provided in the following versions:

Code No.	Needle Size	Vented Tip Cap Y/N	Needle Cube Y/N	Protective Shield Y/N
956-610	-	Y	N	N
956-611	22G x 32 mm	Y	Y	N
956-612	23G x 16 mm	Y	Y	N
956-613	22G x 25 mm	Y	Y	N
956-614	22G x 32 mm	Y	N	Y
956-615	23G x 16 mm	Y	N	Y
956-616	22G x 25 mm	Y	N	Y

Intended Use

The safePICO Arterial Blood Sampler is a preheparinized, electrolyte balanced, arterial blood sampler for collection of arterial samples for pH, blood gas, oximetry, electrolyte and metabolite analyses. The safePICO is a vented sampler for sample volumes in the range from 0.7 to 1.5 mL. The safePICO includes a vented tip cap allowing the sampler to be vented after the appliance of the tip cap and may include a needle shield device to prevent a user from accidental needle stick.

Performance test

The following tests were performed on the prototype of the safePICO sampler:

- Air entrapment
- Parameter values

The following tests were performed on the prototype of the vented tip cap:

- Maximum holding pressure
- Ventilation
- Penetration of ABL800 FLEX inlet probe
- Friction of ABL800 FLEX inlet probe

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The following tests were performed on the prototype of the needle shield device:

- Initial activation force
- Forward displacement force
- Shield lock force
- Unlocking force

The results of the tests showed no new issues of safety and effectiveness.

Further, a large comparison study has been performed between the *safePICO* Arterial Blood Sampler and the predicate device the PICO70 Arterial Blood Sampler, both used on an ABL800 FLEX Analyzer. The study showed that the *safePICO* Arterial Blood Sampler performs substantially equivalent to the predicate device, the PICO70 Arterial Blood Sampler.

Finally, a large Simulated Use Study has been performed on the *safePICO* with Needle Shield Device and the predicate device Pro-Vent with Needle Pro. This study showed that the *safePICO* with Needle Shield Device is at least as safe and effective as the Pro-Vent with Needle Pro.

Additional Safety Information

Manufacturing controls include visual, functional and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with:

ISO/CD 11135: 2001: Sterilization of health care products - Requirements of development, validation and routine control of a sterilization process for medical devices - Ethylene oxide.

EN550: 1994: Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization

The *safePICO* is sterilized to a Sterility Assurance Level (SAL) of 10^{-6} .

Conclusion

The *safePICO* sampler is substantially equivalent in features and characteristics to the predicate devices, PICO Arterial Blood Sampler (K962158) and PRO-VENT (K011925).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 22 2005

Ms. Lene Meineche Marnæs
Regulatory Affairs
Radiometer Medical APS
Åkandevvej 21
Brønshøj,
Denmark DK-2700

Re: k043143
Trade/Device Name: *safe*PICO
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, MEG
Dated: March 18, 2005
Received: March 21, 2005

Dear Ms. Marnæs:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

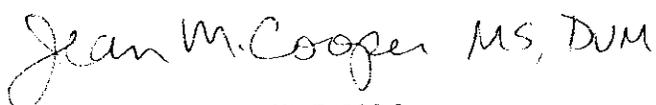
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

March 18, 2005

Indications for Use

510(k) Number: K043143

Device Name: safePICO

Indications For Use:

The safePICO Arterial Blood Sampler is a preheparinized, electrolyte balanced, arterial blood sampler for collection of arterial samples for pH, blood gas, oximetry, electrolyte and metabolite analyses. The safePICO is a vented sampler for sample volumes in the range from 0.7 to 1.5 mL. The safePICO includes a vented tip cap allowing the sampler to be vented after the appliance of the tip cap and may include a needle shield device to prevent a user from accidental needle stick.

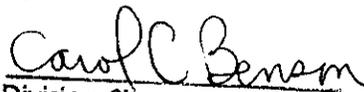
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

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Office of in Vitro Diagnostic
Device Evaluation and Safety

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