

BIO-TEK 510(k) Index 2 E, F, EF & CardioSat 100 E, F, EF APPENDIX G

TEL: 800/451-5172

FAX: 802/655-7941

OUTSIDE THE USA TEL:

802/655-4740

E-MAIL: sales@biotek.comWEB SITE: <http://www.biotek.com>**1- 510(k) SUMMARY**

2- Contact Person: Michael N. Sevigny Quality Assurance Manager
802-655-4040 ext 336
Establishment Registration Number: 1217454
Preparation date April 4, 1997



3- Classification Name: Oximeter (Pulse), accessory to, 74 DQA, and Ear Oximeter, accessory to, 74 DPZ; Cardiovascular Panel; Oximeters Class 2 per 21 CFR §870.2700 Ear Oximeters Class 2 per 21 CFR §870.2710
Common Name: Oximeter Simulator, Analyzer or Tester
Proprietary Name: *Index 2 E, F, EF & CardioSat 100 E, F, EF*

4- Substantially Equivalent to: The device family is equivalent to the legally marketed predicate devices: Bio-Tek Instruments, Inc. *Index*, K933519, SpO₂ Simulator which has many of the same features for total oximeter testing; and to the Clinical Dynamics Corp. SmartSat™ Pulse Oximetry Analyzer, K952327 primarily in the area of electrical simulation of the pulse oximeter and the testing of oximeter probes.

Index 2 and CardioSat 100 and the predicate Pulse Oximeter testers have an identical intended use and there are no new technological features or issues which would raise concern of safety and effectiveness.

5 & 6- Description of Device and Intended Use: The device family is intended for use as simulators, testers/analyzers for Pulse Oximeters, and their probes. The Oximeter tests can be conducted through a simulated human "finger" (F and EF models) or electronically (E and EF models) as if the tester is a probe. Oximeter probes can be tested, using E and EF models, for shorts, continuity, opens and LED functionality.

Basically the devices allow accurate monitoring and verification of the operation of commercially available Pulse Oximeters without use of arterial blood. They can quickly establish the state of any given pulse oximeter and determine its performance qualities. *Index 2/CardioSat 100* can test and evaluate virtually any pulse oximeter on the market today. Ear and toe type oximeters and their probes can be tested electronically as components and the probe/oximeter system can be tested fully if the probe fits on the simulated "finger".

The testers can also be used as a transfer standard for Pulse Oximeters. That is, a Pulse Oximeter's performance may be compared to another of the same type or a different type.

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The devices are not intended to be used as Pulse Oximeter calibrators, but can be used for Quality Control purposes.

The primary use for these types of devices is: by Biomedical Engineers and technicians in Hospitals; by third party repair and calibration facilities; and by Original Equipment Manufacturers (OEMs). Other personnel could also learn how to use the devices. The Hospital or third party repair environment varies from, use of the device in a controlled calibration lab, to portable ward use by the Biomed staff. The OEMs use of the device would primarily involve final QC of pulse oximeters in their manufacturing or repair facilities, but could also involve the use of these simulators in the development of new oximeters.

7- Summary of technological characteristics of devices compared to predicate:

Index 2/CardioSat 100 simulates a human "finger" (toe/ear).utilize technology similar to that which the Pulse Oximeters utilize to measure SpO₂ and pulse rate. This aspect of the technology used in *Index 2/CardioSat 100* is protected by US Patent No. 5,348,005. Oximeters use the ratio of Red to InfraRed light to simulate readings related to the partial pressure and thus arterial oxygenation level of blood, which is expressed as SpO₂ for this method of measurement. In *Index 2/CardioSat 100* the pulsation of the signal serves to simulate the heart rate pulsation. This feature is identical to the predicate *Index*, K933519, SpO₂ Simulator with the addition of a near simultaneous pulsing of the Red and InfraRed LEDs to test a wider range of Pulse Oximeter manufacturers models. Most Pulse Oximeters alternate the Red and InfraRed signals.

The simulators can also send this same types of signals electronically to the Oximeter under test simulating the Oximeter Probe's signal. Additionally, they can operate as intelligent volt/ohmmeters to analyze Oximeter Probes for continuity, shorts, opens, LED operation and Photodiode Operation. These last two features are similar in technology to the Clinical Dynamics Corp. SmartSat™ Pulse Oximetry Analyzer, K952327.

Index 2 and CardioSat 100 and the predicate Pulse Oximeter testers have an identical intended use and there are no new technological features or issues which would raise concern of safety and effectiveness.

8- Performance Testing: (Verification and Validation): The predicate *INDEX* design was extensively verified and validated to be working per the design and published specifications. Many of the features have not changed so this work formed the basis for the new verification/validation plan. The *Index 2 and CardioSat 100* is being and will be fully verified and validated per a written plan prior to release. This plan includes verification/validation that the device features work as intended over a wide range of Oximeter types and in some cases involves external confirmation of the features integrity (e.g. use a volt/ohm meter to determine appropriate outputs etc.).

9- Clinical Testing: Clinical testing was not required since the devices comprise test equipment, and are never in contact with a patient nor do they have any therapeutic or

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diagnostic patient function. As stated above they are not intended to be used as calibrators and should not be used for clinical "calls".

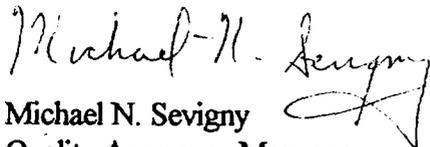
10- Conclusions from testing: The testing conducted to date and that will be conducted prior to release will support all product claims for intended use including accuracy and full feature operation.

11. Other Information of Interest to FDA:

Potential System Hazards: Are classified as those which could affect the functionality of the system and or give erroneous results. The primary system function hazards which were reviewed and addressed were: a) EMC testing indicted that the system meets current CE Mark requirements and will neither interfere with, nor be susceptible to interference from other devices in the ranges given by the IEC standards. b) A Low battery cutoff/alarm is in the design to prevent false but believable results due to electronic circuits operating outside of their specified range. c) To ensure correct operation a known voltage, generated internally, is measured at the start of each probe check sequence.

User Safety Considerations: The device has been designed as a low voltage battery operated device and is thus intrinsically safe. Bio-Tek supplies a UL approved 110V battery charger with the instrument for North American sales.

The above information is certified to be truthful and accurate to the best of my knowledge.


Michael N. Sevigny
Quality Assurance Manager



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 8 1997

Mr. Michael N. Sevigny
Bio-Tek Instruments, Inc.
Highland Park, Box 998
Winooski, Vermont 05404-0998

Re: K971273
Models Index® -2E, -2F, -2FE and Cardiosat™ 100 Pulse Oximeter
Simulators, Analyzers/Testers
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: July 31, 1997
Received: August 4, 1997

Dear Mr. Sevigny:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971273

Device Name: *Index 2 E, F FE and CardioSat 100 E, F, EF Pulse Oximeter Simulators, Testers/Analyzers*

Indications For Use: The above device family is intended for use as simulators, testers/analyzers for Pulse Oximeters, and their probes. The Oximeter tests can be conducted through a simulated human "finger" (F and EF models) or electronically (E and EF models) as if the tester is a probe. Oximeter probes can be tested, using E and EF models, for shorts, continuity, opens and LED functionality.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Page
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971273

Prescription Use _____
(Per 21 CFR §801.109)

OR

Over-The-Counter Use