K031831

DEC 1 9 2003

# 510(K) SUMMARY

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|---|---|
| Applicant: | Topcon Medical Systems, Inc.<br>37 West Century Road, Paramus, NJ 07652 |
| Telephone Number: | (201) 261-9450, ext. 204 |
| Facsimile Number: | (201) 387-2710 |
| Contact Person: | Donald H. Winfield |
| Date: | June 6, 2003 |
| Device Proprietary Name: | Model BV-1000, Automated Subjective Refraction System |
| Device Classification Name: | Refractometer, Ophthalmic |
| Device Common Name: | Refractometer/Auto-refractor |
| Device Class: | I |
| Product Code: | HKO, HOX, HKN |
| Regulation Number: | 886.1760, 886.1150, 886.1770 |
| Intended Use: | The Topcon Model BV-1000 Automated Subjective Refraction System provides sphere, cylinder, and axis measurements of the eye. The BV-1000 assists the eyecare professional in evaluating pre and post operative eye procedures and is used as an aid in prescribing eyeglasses and contact lenses. |

Description:

The Topcon Model BV-1000 is a safe and effective instrument. In essence, it is a combination of three Class I devices:

1) Ophthalmic Refractometer … an AC-powered device that consist of a fixation system, a measurement and recording system and an alignment system.
2) Visual Acuity Chart … a device, with a Landolt "C" chart in graduated sizes to test visual acuity
3) Ophthalmic Motorized Refractor … a device that incorporates a set of lenses of various dioptric powers intended to measure the refractive power of the eye.

The BV-1000 is designed to perform binocular, simultaneous auto-refraction. It incorporates subjective refinement steps after the objective measurements have been obtained. The BV-1000 reduces the amount of time that eyecare professionals need to spend in refracting their patients as a substantial portion of the traditional refraction can be accomplished in the "pre test" room.

## COMPARISONS

| Manufacturer / Distributor | Model | Objective Refraction | | Subjective Refraction | | | | Range |
|---|---|---|---|---|---|---|---|---|
| | | Method | Illumination | Distance | Near | Method | Illumination | |
| Bausch & Lomb | IVEX | Manual Retinoscopy | Halogen | X | X | Snellen Charts; Jackson Cross Cylinder | Fluorescent | (S) -28.00D to +19.75D<br>(C) 0 to -7.75D<br>(A) 0° to 180° |
| Reichert Ophthalmic Instruments | SR-IV | Manual Retinoscopy | Halogen | X | X | Snellen Charts; Simulcross Cross Cylinder | Tungsten | (S) -20.00D to +20.00D<br>(C) 0 to ±8.00D<br>(A) 0° to 180° |
| Zeiss-Humphrey | 515/530/ 560/570 | Built-In Continuously Variable Sphere & Cylinder | 680nm LED | X | X | Cross Cylinder | Tungsten | (S) -12.00D to +20.00D<br>(C) 0 to ±6.00D<br>(A) 0° to 180° |
| Topcon | 6500 | Built-In Rotary Prism | 680nm LED | X | X | Snellen Charts; Jackson Cross Cylinder | Tungsten | (S) -25.00D to +22.00D<br>(C) 0 to ±7D<br>(A) 0° to 180° |
| Topcon | 7000S | Built-In Rotary Prism | 680nm LED | X | X | Snellen Charts; Presbyopic Charts | Tungsten | (S) -25.00D to +22.00D<br>(C) 0 to ±7D<br>(A) 0° to 180° |
| Topcon | BV-1000 | Built-In Rotary Prism | 680nm LED | X | X | Landolt Charts; Jackson Cross Cylinder | Tungsten | Objective Mode:<br>(S) -25.00D to +22.00D<br>(C) 0.00D to -8.00D<br>(A) 1° to 180°<br>Subjective Mode:<br>(S) -18.00D to +18.00D<br>(C) 0.00D to -8.00D<br>(A) 1° to 180° |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Topcon Corporation
c/o Donald H. Winfield
Topcon Medical Systems, Inc.
37 West Century Road
Paramus, NJ 07652

Re: K031831
Trade/Device Name: Topcon Model BV-1000 Automated Subjective Refraction System
Regulation Number: 21 CFR 886.1760; 21 CFR 886.1150; 21 CFR 886.1770
Regulation Name: Ophthalmic refractometer; Visual acuity chart; Manual Refractor
Regulatory Class: Class I
Product Code: HKO; HOX; HKN
Dated: September 17, 2003
Received: September 22, 2003

Dear Mr. Winfield:

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 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 Office of Compliance at (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## STATEMENT OF INDICATION FOR USE

The Topcon Model BV-1000 Automated Subjective Refraction System provides sphere, cylinder and axis measurements of the eye. The BV-1000 assists the eyecare professional in evaluating pre and post operative eye procedures and is used as an aid in prescribing eyeglasses and contact lenses.

Prescription Use MKB Nicholas
(Per 21 CFR 801.109)

MKB Nicholas
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K031831