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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K964312

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Device Name

Proprietary Name: MENTOR® TONO-PEN 3

Common Name: Ocular Tonometer

Classification Name: Tonometer, Manual

Substantial Equivalence

MENTOR TONO-PEN 3 is similar in indications, design and features to MENTOR TONO-PEN XL

Device Description

The MENTOR TONO-PEN 3 is a precision electronic tonometer which measures intraocular pressure [IOP]. The body of the instrument is specially designed to fit comfortably in the user's hand, facilitating fast and accurate measurements.

TONO-PEN 3 contains an elemental silicon strain gage which converts intraocular pressure to an electrical signal. The pen displays each valid reading on a liquid crystal display [LCD]. When four valid readings are obtained, a mean IOP reading and an indication of reliability are shown on the LCD. The TONO-PEN 3 has a molded plastic tip which must be covered by a latex protective membrane. MENTOR Ocu-Film Tip covers are recommended.

Intended Use


The MENTOR TONO-PEN 3 is used to measure the intraocular pressure (IOP) during routine eye examination or when an increased IOP is suspected.

Substantial Equivalence Comparison

	MENTOR TONO-PEN 3	MENTOR TONO-PEN XL
Indication	Intraocular pressure (IOP) measurement.	Same
Design	Hand-held, microprocessor based.	Same
Transducer	Elemental silicon, diaphragm type strain gage transducer.	Precision stainless steel plunger on a strain gage force transducer.
Calibration	Not necessary	Needed
Distal tip	Si diaphragm	Stainless steel
Tip cover	Latex protective membrane	Same
User interface	The TONO-PEN III is held as you would a pencil, with the index finger on the activation switch. Once activated, the user touches the cornea lightly and briefly and withdraws the TONO-PEN III. A reading will be displayed on the LCD. After four readings an average will appear as well as the reliability of the average number shown.	Same
Computer interface	There is a computer interface jack located on the underside of the unit.	Same
Display	Liquid Crystal Display	Same
Range of measurement	5-80 mm Hg	Same
Statistical reliability	The display of four horizontal bars across the lower border of the LCD block indicate the statistical reliability of the averaged measurement. For example, if the 5% bar is displayed, the standard deviation of the valid measurements is 5% or less of the average number shown.	Same
Versatility	Can be used in cases of irregular or high corneal astigmatism. It may be used with the patient in any position, making it suitable for the office, during surgery, in clinics, at the bedside or in remote locations.	Same

	MENTOR TONO-PEN 3	MENTOR TONO-PEN XL
Weight	2.0 ounces	2.6 ounces
Dimensions	7 1/4" x 1" x 7/8"	Same
Power source	2 ea. 3.0 volt lithium manganese dioxide batteries	Same

The determination of substantial equivalence is not based on an assessment of any performance data, clinical or non-clinical.


 Submitter's Signature

10-15-96
 Date