1. TITLE PAGE

Protocol Title:	Comparative study of the NIDEK TONOREF III and the Haag-Streit Goldmann Manual Tonometer (Predicate) to demonstrate conformance to ANSI Z80.10-2014 Ophthalmic Instruments – Tonometers, to the FDA Guidance for Industry and FDA Staff, Tonometer-Premarket Notification [510(k)] Submissions, and to the applicable Supplemental Information Sheet and comparison of pachymetry values for NIDEK TONOREF III with the NIDEK CEM-530 (Predicate)
Protocol Number:	NIDEK-TONOREF-US-0001
Product Name:	NIDEK TONOREF III
Proposed Indications for use:	The auto ref/kerato/tono/pachymeter TONOREF III is a medical device which measures objective refractive errors, corneal curvature radius, intraocular pressure and corneal thickness of the patient's eye.
Site/Investigators:	Multicenter
Sponsor:	NIDEK Co., LTD
	34-14 Meahama, Hiroishi-cho, Gamagori, Aichi, 443-0038 Japan
NCT Number:	NCT03441477
Document Date:	IRB approval on November 7, 2017

2. STUDY PROTOCOL

This was a prospective clinical study to be conducted at multiple clinical sites located in the United States. This clinical device study assessed the substantial equivalence of NIDEK TONOREF III to a predicate devices regarding tonometry and pachymetry.

Three sets of devices consisting of the following machines - TONOREF III, Haag-Streit Goldmann Manual Tonometer (GAT) and NIDEK CEM-530 were used. The device order of measurements captured on the predicate and investigational devices were randomized. This was an open-label study, meaning all study staff and subjects

were aware of which devices were being used. However, the investigators were blinded to the results obtained by each device, to protect against observer bias.

Eligible subjects were measured by all study devices and the safety of the devices were also assessed. The study period was one day.

3. STATISTICAL ANALYSIS PLAN

The mean IOP value measured with the NIDEK TONOREF III minus the IOP value measured with the predicate tonometer (GAT) equals the difference between the test and predicate tonometer.

Descriptive statistics, including mean and standard deviation of the differences between the test device and the GAT, Bland and Altman plot and linear regression were analyzed. The first 40 qualified eyes in each pressure range only will be used for the above analysis

The mean corneal thickness values measured with NIDEK TONOREF III minus the corneal thickness value measured with the predicate pachymeter (CEM-530) equals the difference between the test and predicate pachymeter.

Descriptive statistics, including mean difference and standard deviation of the differences between the test device and the CEM-530, Bland and Altman plot and Deming regression were analyzed.

Any sight threatening adverse event associated with the TONOREF III or the predicate devices including subject complaints and clinical observations of corneal abrasions were collected.

The data analysis included a comparison of the frequencies of all adverse events and adverse device effects. Adverse events reported were listed by subject and subject complaints and corneal abrasions for the test and reference devices were specified.