Contains Nonbinding Recommendations

Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders and the FDA webpage titled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20025 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-Ophthalmic@fda.hhs.gov.

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Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID-19 during this pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service (PHS) Act.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," available at https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named SARS-CoV-2 and the disease it causes has been named Coronavirus Disease 2019 (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by helping to expand the availability and capability of remote ophthalmic assessment and monitoring devices. Modified use of these devices may facilitate patient management by health care providers while reducing the need for in-person treatment during the COVID-19 public health emergency and may help reduce the risk of exposure for patients and health care providers to SARS-CoV-2.

III. Scope

The enforcement policies described in this guidance apply to the following devices that assess or monitor ophthalmic parameters. These devices have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's ophthalmic parameters directly to their eye care provider or other monitoring entity. Some of these devices also have the potential to apply algorithms to transform a patient's ophthalmic parameters into a novel

[1] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

index or alarm that may aid an eye care provider in the diagnosis of a particular condition or disease state/severity or be used in the context of a telemedicine visit, with the patient at home, allowing the eye care provider to assess specific ophthalmic parameters remotely.

A. Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras

Visual acuity charts, visual field devices, and general-use ophthalmic cameras allow assessment and/or imaging of the eye to assist eye care providers in detecting or monitoring the progression of ocular conditions or diseases. Visual acuity charts are charts that are used to test the clarity or sharpness of vision. Visual field devices include perimeter devices used to test the peripheral visual field, as well as Amsler grids used to test the central visual field. General-use ophthalmic cameras are devices that are used to take photographs of the eye and surrounding area. In general, these devices are exempt from premarket notification [510(k)] requirements, but may remain subject to other general controls, such as Registration and Listing requirements in 21 CFR Part 807. The classification regulations and associated product codes for these devices, to which the policy in this guidance applies, are listed in Table 1:

Table 1 - Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras

Classification Regulation	Device Type	Product Code[3]	Device Classification
21 CFR 886.1120	Camera, Ophthalmic, General-use	PJZ	II (exempt)[4]
21 CFR 886.1150	Visual Acuity Chart	HOX	I (exempt)[5]
21 CFR 886.1330	Amsler Grid	HOQ	I (exempt)[6]
21 CFR 886.1605	Perimeter, AC-powered	HOO	I (exempt)[7]
21 CFR 886.1605	Perimeter, Automatic, AC-powered	HPT	I (exempt)[8]

[3] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[4] These devices are exempt from submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, subject to the limitations in 21 CFR 886.9. FDA clearance is not required before marketing the device in the United States; however, manufacturers are required to register their establishment and comply with other postmarket reporting requirements.

[5] These devices are exempt from submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, subject to the limitations in 21 CFR 886.9; however, manufacturers are required to register their establishment. The device type is also exempt from the current good manufacturing practice requirements of the quality system regulations in 21 CFR 820, with the exception of records (see 21 CFR 820.180) and complaint handling (see 21 CFR 820.198). FDA clearance is not required before marketing the device in the United States; however, manufacturers are required to register their establishment.

[6] *Ibid*.

[7] *Ibid.*

[8] *Ibid.*

B. Tonometers

Tonometers are devices intended to measure intraocular pressure by applying a known force on the globe of the eye and measuring the amount of indentation or force produced or to measure intraocular tension by applanation (applying a small flat disk to the cornea). In general, manufacturers of tonometers are required to submit a premarket notification pursuant to section 510(k) of the FD&C Act and 21 CFR 807.81 to FDA and receive FDA clearance prior to marketing these devices in the United States, as well as comply with postmarketing requirements. The classification regulation and associated product codes for tonometers, to which the policy in this guidance applies, are listed in Table 2:

Table 2 - Tonometers

Classification Regulation	Device Type	Product Code[9]	Device Classification
21 CFR 886.1930	Tonometer, AC-powered	HKX	II
21 CFR 886.1930	Tonometer, Manual	HKY	II

IV. Policy

In the context of the COVID-19 public health emergency, expanding the capability of remote ophthalmic assessment and monitoring devices may help facilitate patient care while reducing patient and healthcare provider contact and risk of exposure to SARS-CoV-2.[10] For that reason, FDA does not intend to object to limited modifications to the indications, functionality, hardware, and/or software, of 510(k)-cleared devices for remote assessment and monitoring of ophthalmic parameters, or distribution and use of these device types that are exempt from submission of a 510(k), during the declared public health emergency without compliance with certain regulatory requirements, as discussed in further detail below, where such devices do not create an undue risk in light of the public health emergency. Examples of such modifications include:

- For devices previously intended for use in healthcare facilities, a change to the indications regarding use in the home setting;
- Modifications of non-portable devices to include portable or handheld device features;
- Modifications to devices, including changes in hardware or software, to include virtual reality or mobile technology for remote assessment or monitoring capability.

In developing this policy, FDA's intent is to foster the continued availability of safe and effective medical devices while being flexible regarding modifications made to devices for remote assessment

[9] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[10] In a press release dated March 18, 2020 (available at https://www.aao.org/newsroom/news-releases/detail/ophthalmologists-urged-to-cease-non-emergency-care), the American Academy of Ophthalmology recommended that all ophthalmologists immediately cease providing any in-person treatment other than urgent or emergent care.

and monitoring of ophthalmic parameters in response to the COVID-19 public health emergency.

A. Modifications to the Indications and Functionality of Remote Ophthalmic Assessment and Monitoring Devices

(1) Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras

For the duration of the public health emergency, FDA does not intend to object to limited modifications to the indications, functionality, hardware, and/or software, of the devices in Table 1 without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81[11], where such submission would be required,[12] Quality System Regulation requirements in 21 CFR Part 820 where such requirements are applicable, Reports of Corrections and Removals requirements in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Examples of circumstances where FDA currently believes a modification to a device in Table 1 would not create such undue risk include:

1) Indications and functionality designed to permit the use of the device for monitoring and/or assessment of the ophthalmic parameters, if such devices are not indicated or designed for such.
2) Indications and functionality designed to permit the use of the device for home use and/or by consumers rather than eye care providers.
3) Indications and functionality designed to permit the use of the device for a telemedicine consultation, allowing the eye care provider to assess specific ophthalmic parameters remotely.
4) Devices containing software and/or hardware intended to implement intended device functionality for use directly by consumers at home (e.g., visual acuity assessment, visual field assessment, image capture).
5) Devices containing software and/or hardware intended to facilitate remote access (e.g., addition of wireless or Bluetooth capability).

Examples of circumstances where FDA currently believes distribution and use of the device or modifications to these devices would create such an undue risk include:

[11] For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

[12] Certain modifications to the indications and functionality of these devices may require premarket notification subject to the limitations of the exemption under 21 CFR 886.9.

1) The device is intended to determine when patients need immediate clinical intervention to assure patient safety; or
2) The device is intended to be solely or primarily relied upon by the eye care provider or patient to make a clinical diagnosis or treatment decision.

(2) Tonometers

For the duration of the declared public health emergency, FDA does not intend to object to limited modifications to the indications, functionality, hardware, and/or software, of the devices in Table 2 without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency. FDA currently believes a modification does not create such undue risk in the following scenario:

1) The device is intended only for the purpose of measuring intraocular pressure;
2) The device is handheld or portable;
3) The mechanism of measurement is either non-contact, rebound, or transpalperbral;
4) The device is intended for the purpose of supporting or providing adjunctive recommendations to the eye care provider or patient about prevention, diagnosis or treatment of ocular conditions; and
5) The eye care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations.

Examples of circumstances where FDA currently believes a modification would create such an undue risk include:

1) The device is intended to determine when patients need immediate clinical intervention to assure patient safety;
2) The device is intended to be solely or primarily relied upon by the eye care provider or patient to make a clinical diagnosis or treatment decision;
3) The modifications add the functionality to acquire, process, or analyze a pattern or signal from a signal acquisition system that was not present in the FDA-cleared device; or
4) Modifications are made to device components that have direct contact with the eye.

B. Validation of Modifications to the Functionality of Remote Ophthalmic Assessment and Monitoring Devices

In designing, evaluating, and validating modifications made under this policy to hardware and/or software, FDA recommends doing so in accordance with FDA recognized standards for the specific device type, including (as applicable):

- ANSI/AAMI ES60601-1:2005 (R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012: – *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- ANSI/AAMI/IEC 60601-1-2:2014 – *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11:2015 – *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- ANSI Z80.21-2010 (R2015) *American National Standard for Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts*
- ISO 10940-2009 *Ophthalmic Instruments - Fundus Cameras*
- ANSI Z80.10-2014 *American National Standard for Ophthalmics - Ophthalmic Instruments – Tonometers*
- ISO 15004-1 First Edition 2006-06-01 *Ophthalmic Instruments - Fundamental Requirements and Test Methods - Part 1: General Requirements Applicable to All Ophthalmic Instruments*
- ANSI Z80.36-2016 *American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments*
- AAMI TIR69: 2017 – *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017 – *American National Standard for Evaluation of Wireless Coexistence*
- ANSI/AAMI/IEC 62304 – *Medical Device Software – Software Life Cycle Processes*

For any such hardware and/or software changes, FDA also recommends considering the following FDA guidance documents related to common device modifications:

- Radio Frequency Wireless Technology in Medical Devices[13]
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices[14]

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[15] For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[16]

In addition, for any such changes, manufacturers should develop and implement appropriate

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.
[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.
[15] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

cybersecurity controls to assure device cybersecurity and maintain device functionality and safety. The following online resources may be helpful in developing and maintaining these cybersecurity controls:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices[17]
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices[18]
- Postmarket Management of Cybersecurity in Medical Devices[19]

C. Labeling of Modified Devices

In addition, FDA recommends that the devices described in this guidance use labeling that helps users better understand the device modifications. FDA recommends that the labeling include the following elements:

1) A clear description of the available data on the device's new indications, and/or functions including information regarding:
   a. Device performance;
   b. Method of determining any diagnostic or treatment recommendations; and
   c. Potential risks.
2) Adequate instructions for use for the intended user and indicated environment(s) of use. The labeling should highlight the differences in design compared to the unmodified version of the device, along with instructions for mitigating any known risks associated with these differences.
3) Information so that the eye care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations.
4) For devices previously cleared for use only in a hospital or other health care facility and for which the environment of use has been expanded to include in-home use, adequate instructions for use in the home setting with appropriate lay terminology.
5) For FDA-cleared devices, clear distinction delineating FDA-cleared indications from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA. For exempt devices listed in Table 1, FDA recommends that the labeling include a statement about indications outside the limitations of exemption in 21 CFR 886.9 for that device type.
6) A prominent notice to both the patient and eye care provider that recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to prevent, diagnose, or treat ocular conditions.

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices.