TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity resulting from Section 510(p) of the FD&C Act as amended by FDAAA	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
One-time preparation of SOP	1,000	1	1,000	40	40,000
SOP maintenance	3,295	1	3,295	1	3,295
Total	43,295				

[1] There are no capital costs or operating and maintenance costs associated with the collection of information.

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16129 Filed 6–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2044]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Enterovirus D68; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for in an vitro diagnostic device for detection of Enterovirus D68 (EV–D68) strains detected in North America in 2014. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 6, 2015, determination by the Department of Health and Human Services (HHS) Secretary that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves EV–D68. On the basis of such determination, the Secretary of HHS also declared on February 6, 2015, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic devices for detection of EV–D68 subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of May 12, 2015.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Acting Assistant Commissioner for Counterterrorism Policy and Acting Director, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of CDC (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Request for an In Vitro Diagnostic Device for Detection of EV–D68

On February 6, 2015, under section 564(b)(1)(C) of the FD&C Act (21 U.S.C. 360bbb–3(b)(1)(C)), the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves EV–D68. Also on February 6, 2015, under section 564(b)(1) of the FD&C Act and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of EV–D68, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on February 27, 2015 (80 FR 10685). On April 24, 2015, CDC requested, and on May 12, 2015, FDA issued, an EUA for the CDC EV–D68 2014 Real-time RT–PCR Assay, subject to the terms of the Authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *http://www.regulations.gov.*

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of EV–D68 strains detected in North America in 2014 subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164–01–P

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

May 12, 2015

Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Centers for Disease Control and Prevention's (CDC) Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR) for the *in vitro* qualitative detection of RNA from the enterovirus D68 (EV-D68) strains detected in North America in 2014 in upper respiratory specimens (such as nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, dual NP/OP swabs, and/or nasal washes) and sera in conjunction with patient-matched upper respiratory specimen(s) from individuals with signs and symptoms of EV-D68 infection and/or epidemiologic risk factors, by qualified laboratories designated by CDC on specified instruments, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On February 6, 2015, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves EV-D68.[1] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for the detection of EV-D68, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[2]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the EV-D68 2014 rRT-PCR (as described in the Scope of Authorization section of this letter (section II)) in individuals with signs and symptoms of EV-D68 infection and/or epidemiologic risk factors (as described in the Scope of Authorization section of this letter (section II)) for the *in vitro* qualitative detection of EV-D68 strains detected in North America in 2014.

[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[2] HHS. *Determination and Declaration Regarding Emergency Use of New In Vitro Diagnostics for Detection of Enterovirus D68.* 80 Fed. Reg. 10685 (February 27, 2015).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the EV-D68 2014 rRT-PCR for the *in vitro* qualitative detection of EV-D68 strains detected in North America in 2014 in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. EV-D68 can cause EV-D68 infection, a serious or life-threatening disease or condition to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the EV-D68 2014 rRT-PCR, when used with the specified instruments, may be effective in diagnosing EV-D68 infection, and that the known and potential benefits of the EV-D68 2014 rRT-PCR for diagnosing EV-D68 infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the EV-D68 2014 rRT-PCR for diagnosing EV-D68 infection.[3]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized EV-D68 2014 rRT-PCR by qualified laboratories designated by CDC for the *in vitro* qualitative detection of EV-D68 strains detected in North America in 2014 in individuals with signs and symptoms of EV-D68 infection and/or epidemiologic risk factors.

The Authorized Enterovirus D68 2014 Real-time RT-PCR Assay

The EV-D68 2014 rRT-PCR is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of EV-D68 strains detected in North America in 2014 in upper respiratory specimens (such as NP swabs, OP swabs, dual NP/OP swabs, and/or nasal washes), sera in conjunction with patient-matched upper respiratory specimen(s), and other authorized specimen types from individuals with signs and symptoms of EV-D68 infection and/or epidemiologic risk factors. The test procedure consists of nucleic acid extraction using the QIAamp Viral RNA Mini Kit, QIAamp DSP Viral RNA Mini Kit, bioMérieux easyMAG, or other authorized extraction methods, followed by rRT-PCR on Applied Biosystems PCR instrument systems (i.e., AB 7500, AB 7500 Fast, and AB 7500 Fast Dx Real-Time PCR Systems with SDS software) or other authorized instruments.

The EV-D68 2014 rRT-PCR is based on one-step real-time reverse transcription polymerase chain reaction. The Assay employs one primer and probe set (VP1.2014) that targets the viral protein 1 (VP1) gene of the EV-D68 genome, and one primer and probe set (RP) that targets the human RNase P gene.

[3] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

The EV-D68 2014 rRT-PCR uses the following primer/probe sets:

VP1.2014: targets the EV-D68 viral protein 1 (VP1) gene

RP[a]: targets the human Ribonuclease P gene. This primer and probe set is included as a control for specimen quality, to confirm that human nucleic acid was successfully extracted from the clinical specimen.

The EV-D68 2014 rRT-PCR includes the following assay controls:

1. EV-D68 2014 rRT-PCR Positive Control is comprised of synthetic, *in vitro* transcribed single-stranded, positive–sense RNA transcript.

2. RNase P Primer and Probe Set is run on all clinical specimens tested with the EV-D68 2014 rRT-PCR as a measure of the presence and quality of nucleic acid resulting from extraction of the clinical specimens.

The above-described EV-D68 2014 rRT-PCR, when labeled consistently with the labeling authorized by FDA entitled "Enterovirus D68 2014 Real-time RT-PCR Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by CDC in consultation with FDA, is authorized to be distributed to, and used by, qualified laboratories designated by CDC under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described EV-D68 2014 rRT-PCR is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care providers and patients:

- Fact Sheet for Health Care Providers: Interpreting CDC's Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR) Results

- Fact Sheet for Patients: Understanding Results from the Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR)

As described in section IV below, CDC and any authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized EV-D68 2014 rRT-PCR that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized EV-D68 2014 rRT-PCR in the specified population, when used for the *in vitro* qualitative detection of EV-D68 strains detected in North America in 2014, outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized EV-D68 2014 rRT-

PCR may be effective in the diagnosis of EV-D68 infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in section I above, and concludes that the authorized EV-D68 2014 rRT-PCR, when used to diagnose EV-D68 infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized EV-D68 2014 rRT-PCR under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (section II) and the Conditions of Authorization (section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the EV-D68 2014 rRT-PCR described above is authorized to diagnose EV-D68 infection in individuals with signs and symptoms of EV-D68 infection and/or epidemiologic risk factors.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the EV-D68 2014 rRT-PCR during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the EV-D68 2014 rRT-PCR.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC and Any Authorized Distributor(s)

A. CDC and any authorized distributor(s) will distribute the authorized EV-D68 2014 rRT-PCR with the authorized labeling, as may be revised only by CDC in consultation with FDA, to qualified laboratories designated by CDC.

B. CDC and any authorized distributor(s) will provide to qualified laboratories designated by CDC the authorized EV-D68 2014 rRT-PCR Fact Sheet for Health Care Providers and the authorized EV-D68 2014 rRT-PCR Fact Sheet for Patients.

C. CDC any authorized distributor(s) will make available on their websites the EV-D68 2014 rRT-PCR Fact Sheet for Health Care Providers and the authorized EV-D68 2014 rRT-PCR Fact Sheet for Patients.

D. CDC and any authorized distributor(s) will inform qualified laboratories designated by CDC and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. CDC and any authorized distributor(s) will ensure that qualified laboratories designated by CDC using the authorized EV-D68 2014 rRT-PCR have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

F. Through a process of inventory control, CDC and any authorized distributor(s) will maintain records of device usage.

G. CDC and any authorized distributor(s) will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which CDC and any authorized distributor(s) become aware.

H. CDC and any authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized EV-D68 2014 rRT-PCR that is consistent with, and does not exceed, the terms of this letter of authorization.

CDC

I. CDC will notify FDA of any authorized distributor(s) of the EV-D68 2014 rRT-PCR, including the name, address, and phone number of any authorized distributor(s).

J. CDC will provide any authorized distributor(s) with a copy of this EUA, and communicate to any authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

K. CDC only may request changes to the authorized EV-D68 2014 rRT-PCR Fact Sheet for Health Care Providers or the authorized EV-D68 2014 rRT-PCR Fact Sheet for Patients. Such requests will be made only by CDC in consultation with FDA.

L. CDC may request the addition of other specimen types for use with the authorized EV-D68 2014 rRT-PCR. Such requests will be made by CDC in consultation with, and require concurrence of, FDA.

M. CDC may request the addition of other extraction methods for use with the authorized EV-D68 2014 rRT-PCR. Such requests will be made by CDC in consultation with, and require concurrence of, FDA.

N. CDC may request the addition of other real-time PCR instruments for use with the authorized EV-D68 2014 rRT-PCR. Such requests will be made by CDC in consultation with, and require concurrence of, FDA.

O. CDC will track adverse events and report to FDA under 21 CFR part 803.

Qualified Laboratories Designated by CDC

P. Qualified laboratories designated by CDC will include with reports of the results of the EV-D68 2014 rRT-PCR the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

Q. Qualified laboratories designated by CDC will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

R. Qualified laboratories designated by CDC will collect information on the performance of the assay, and report to CDC and any authorized distributor(s) any suspected occurrence of false positive or false negative results of which they become aware.

S. All laboratory personnel using the assay will be appropriately trained on the use of the EV-D68 2014 rRT-PCR on the specified Applied Biosystems PCR instrument systems or other authorized instruments, and use appropriate laboratory and personal protective equipment when handling this test.

CDC, Any Authorized Distributors, and Qualified Laboratories Designated by CDC

T. CDC, any authorized distributor(s), and qualified laboratories designated by CDC will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

U. All advertising and promotional descriptive printed matter relating to the use of the authorized EV-D68 2014 rRT-PCR shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

V. All advertising and promotional descriptive printed matter relating to the use of the authorized EV-D68 2014 rRT-PCR shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

Page 7 –Dr. Frieden, Centers for Disease Control and Prevention

- This test has been authorized by FDA under an EUA for use by qualified laboratories designated by CDC;
- This test has been authorized only for the detection of EV-D68; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of EV-D68 under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

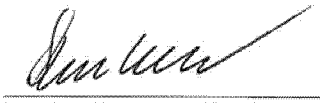
No advertising or promotional descriptive printed matter relating to the use of the authorized EV-D68 2014 rRT-PCR may represent or suggest that this test is safe or effective for the diagnosis of EV-D68.

The emergency use of the authorized EV-D68 2014 rRT-PCR described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of EV-D68 is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosure

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16125 Filed 6–30–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0967]

Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices From Premarket Notification Requirements; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements.'' This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices from premarket notification requirements. FDA believes the devices identified in this guidance document are sufficiently well understood and do not require premarket notification to assure their safety and effectiveness.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.