

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0109]

Distribution Date 2-4-03
Publication Date 2-5-03
Certifier D. Hawkins

**Medical Devices: Class II Special Controls Guidance Document:
Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA." This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH),

ch023

00D-0109

NAD-2

Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2096.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify this type of device from class III to class II. This guidance serves to update the information provided in the draft guidance entitled “Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices” (65 FR 12271, March 8, 2000). FDA considered the comments it received and made changes to the guidance as a result, including the revised document title to identify this guidance as a special control. FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable

assurance of the safety and effectiveness of the fully automated short-term incubation cycle antimicrobial susceptibility device. After the device is reclassified, a manufacturer who intends to market a device of this generic type must: (1) Comply with the general controls of the Federal Food, Drug, and Cosmetic Act, including the 510(k) requirements described in 21 CFR 807.81, (2) address the specific risks to health associated with the antimicrobial susceptibility test system, and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

This guidance document identifies the classification, product code, and classification definition for fully automated short-term incubation cycle antimicrobial susceptibility devices. In addition, it identifies the risks to health and serves as a special control that, when followed and combined with the general controls of the act, will be sufficient to address the risks associated with this generic device type and lead to a timely review and clearance of a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on AST systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations. Following the effective date of the final classification rule (published elsewhere in this issue of the **Federal Register**), any firm submitting a 510(k) premarket notification for a fully automated short-term incubation cycle antimicrobial susceptibility device will need to address the issues covered in the special control guidance. However, the firm need only

show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

III. Electronic Access

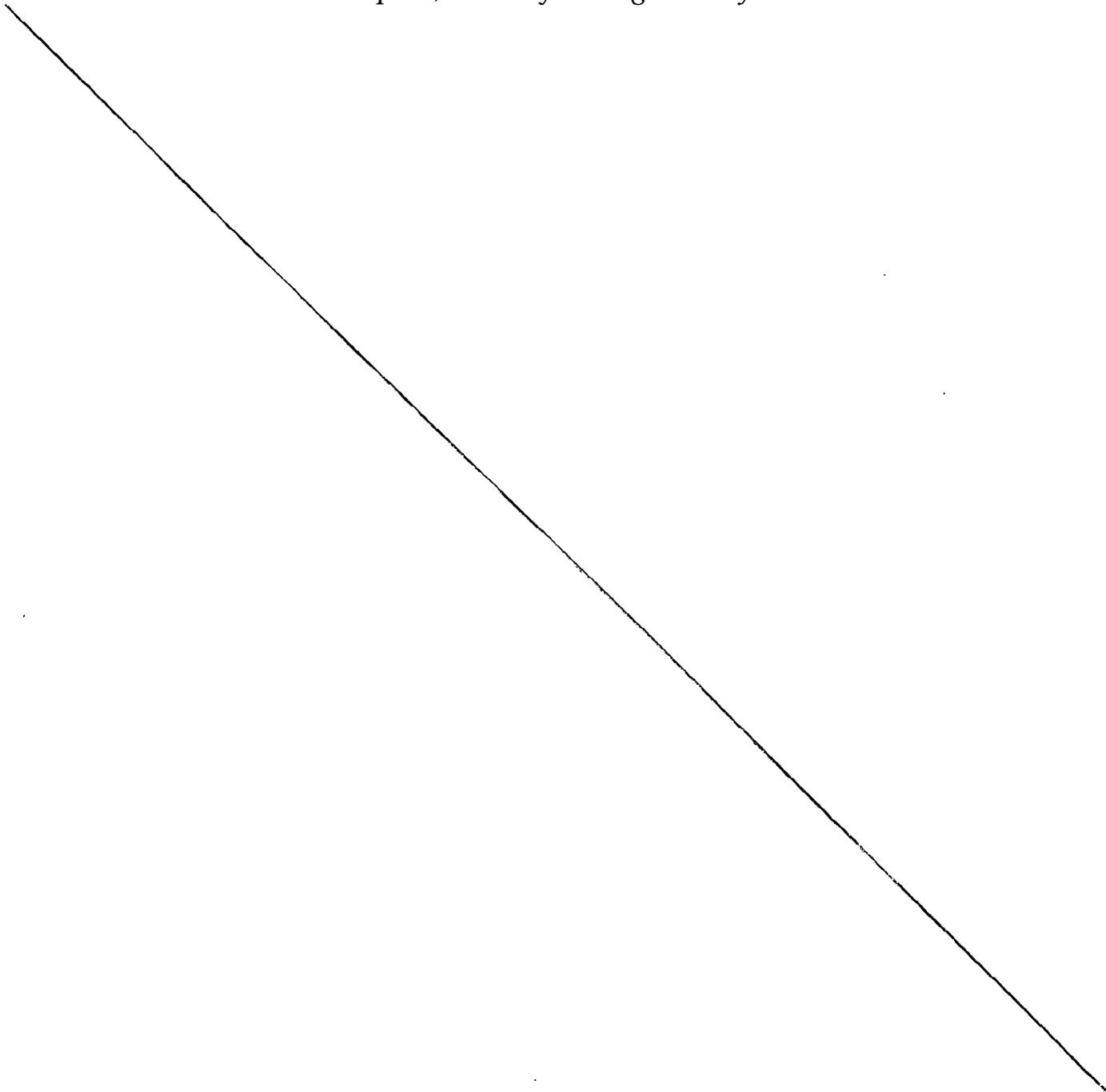
In order to receive “Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA,” you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail to GWA@CDRH.FDA.GOV to request a hard copy or electronic copy. Please use the document number (631) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Comments

Interested persons may submit to Dockets Management Branch (see **ADDRESSES**) written or comments regarding this guidance. Two copies of any

mailed comments, are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Electronic comments may be submitted at <http://www.fda.gov/opacom/backgrounders/voice.html>. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 1/9/03
January 9, 2003.

Linda S. Kahan
Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Dawn P. Hawkins