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Certifier	M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2211]

Medical Devices; Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA." This draft guidance is intended to identify the elements for an investigational device exemption/premarket approval application (IDE/PMA) for any electro-optical sensor in vivo device for the detection of cervical cancer or its precursors. This draft guidance covers electro-optical devices applied to a woman's cervix in an in vivo setting that give a relatively instantaneous reading of test results for the purposes of detection of cervical cancer and its precursors. Many of these systems use complex signal discrimination algorithms and/or neural networks to differentiate abnormal from normal tissue. These new technologies, depending upon design and study results, may ultimately complement, as an adjunct, or replace the PAP smear, or it may serve to improve the results of colposcopy or biopsy. This draft guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft

guidance entitled “Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA” to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 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 Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled, “Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA.” This draft guidance is intended to identify the elements for an IDE and/or a PMA application for electro-optical sensors that are used in a clinical in vivo setting for the detection of cervical cancer or its precursors. This draft guidance is the result of several preliminary interactions between FDA and developers of this type of device, as well as input from experts at a meeting of FDA’s advisory committee, the Obstetrics and Gynecology Devices Panel, on July 14 and 15, 1997. The draft guidance covers various types of hand-held probes that employ electro-optical sensor technology to optically interrogate the cervix uteri for cancer and its precursors. Many of these systems use complex signal discrimination algorithms and/or neural networks to differentiate abnormal from normal tissue; and, generally, these sensors provide a relatively instantaneous reading of test results. The new technology covered by this guidance document, depending upon design and study results, may complement, as an adjunct,

or replace the PAP smear, or it may serve to improve the results of colposcopy or biopsy. These in vivo detection devices apply several different optical phenomena, including autofluorescence and Raman spectroscopy. Some may include bioelectrical phenomena.

This draft guidance document represents the agency's current thinking on the appropriate content of IDE/PMA applications for in vivo devices for the detection of cervical cancer and its precursors. 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 statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a level 1 guidance consistent with GGP's.

II. Electronic Access

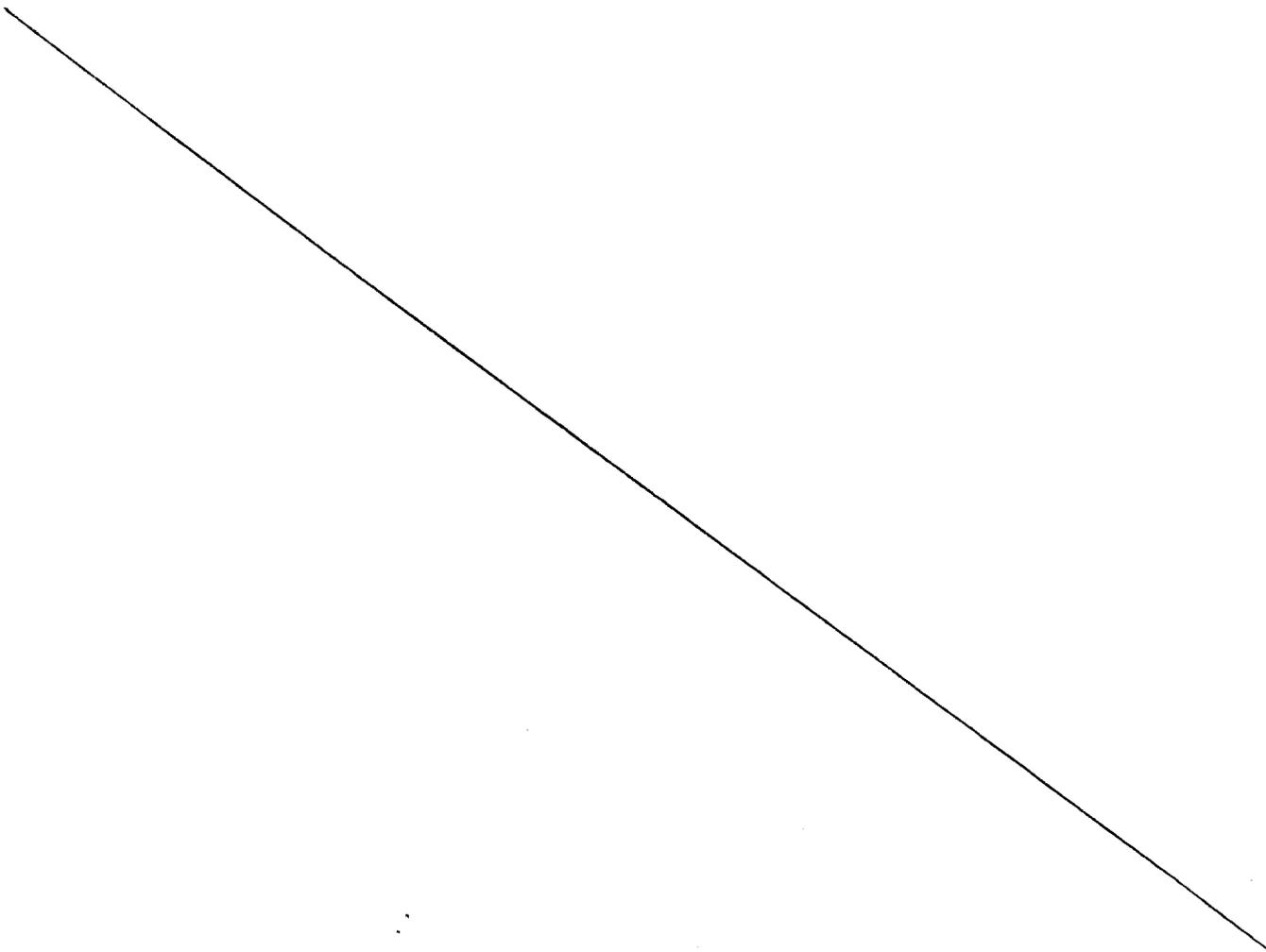
In order to receive "Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (266) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the "Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA," 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>". The "Draft Guidance for Industry on the Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA" will be available at "<http://www.fda.gov/scripts/cdrh/ctdocs/cfggp/results.cfm>".

III. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets



in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/28/99
July 28, 1999

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

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Michael W. Bell