Hello. I'm Elias Mallis, the Director of the Division of Small Manufacturers, International and Consumer Assistance in FDA's Center for Devices and Radiological Health, or CDRH. Welcome to CDRH Learn.

CDRH Learn is a web-based training program that provides industry education on matters pertaining to medical devices and radiation programs.
The program consists of a series of training modules that address timely matters that we believe you'll find to be informative and of interest to you. I hope you that you enjoy this training program.

Today, I'm going to discuss the Guidance Document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications or 510(k)s."

To provide you with some background, this guidance document was published in December 2011 and was issued in draft. This means that this guidance is not intended to be implemented at this time, but instead, is available for review and comment by interested stakeholders. Later in this presentation, I'll discuss how you can send us your comments on this draft guidance.

Over the next few slides, I'll discuss the purpose of this guidance document.

With the issuance of the Medical Device Amendments of 1976, Congress gave FDA the authority to regulate medical devices and created the concept of the 510(k) Program. Over time, the 510(k) program has evolved as laws, regulations, and policies have been introduced. Nevertheless, two existing guidances reflect the current policies with respect to the 510(k) Program. The first guidance is titled "Guidance on the CDRH Premarket Notification Review Program," also known as "CDRH 510(k) Blue Book Memorandum K86-3." This was published in June of 1986. The second guidance is titled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, which was published in March of 1998.

This new draft 510(k) guidance is intended to update and merge these two existing guidance documents. Upon issuance in final, this new guidance would in fact replace those two guidances.

From approximately 2009 to the present time, CDRH has made a focused effort to evaluate the 510(k) Program. This draft guidance is a result of this effort and reflects the changes, clarifications and updates to the 510(k) Program that have been proposed and discussed over the past few years.

This guidance document serves to provide clarity, transparency, consistency, and predictability in the 510(k) decision-making process. The guidance addresses and discusses each of the critical decision points in the substantial equivalence evaluation of a 510(k). The guidance addresses elements identified in the 510(k) Implementation

Plan that was issued by CDRH in January 2011, and the issuance of this guidance was identified as a deliverable action item of this effort.

Over the next few slides, I'll define a few key terms that appear in the guidance document. 510(k). A 510(k) is a premarket notification, a type of medical device application used by manufacturers or sponsors to obtain market clearance for Class I and II medical devices that are not exempt.

Predicate Device. A predicate device is a legally marketed device that is used for comparison to a new device, for the purpose of determining substantial equivalence.

Substantial Equivalence. This is a determination that a new device, as compared to a predicate device, has the same intended use, the same technological characteristics, or differences that don't raise different questions.

Reference device. A reference device is a legally marketed device. It is not a predicate device as defined previously, but is otherwise used to address certain performance characteristics of a new device. I'd like to point out that "reference device" is a new term that is defined in this draft guidance.
Intended Use. The intended use is the general purpose of a device and describes what the devices does.

Indications for Use. The indications for use describes the disease or condition that the device will diagnose, treat, prevent, cure, or mitigate. This term may also define the target patient population.

Regarding the scope, this guidance affects all medical devices that are regulated under 510(k). This includes all 510(k) devices regulated by the Center for Devices and Radiological Health, or CDRH, as well as the Center for Biologics Evaluation and Research, or CBER. This guidance encompasses all key 510(k) Programs, such as the Traditional, Special and Abbreviated
510(k). The guidance is cross-cutting in nature, in that it impacts all medical device areas.

I'll now describe the development process for this guidance document.
The guidance development team was formed in the Spring of 2011. The team featured contributors from each of the impacted program areas and Offices within CDRH, and also included representation from CBER. Because of the significant effort involved with this guidance, the guidance development team worked in sub-teams, each of which addressed a key area of the 510(k) Program. Upon completion of the work by the sub-teams, the overall guidance document team consolidated the individual sub-team efforts, which resulted in the overall guidance that was drafted.
I'll next highlight the key milestones of the guidance development process. In August 2010, the 510(k) Implementation Report was published. This report was based on the work and findings of the 510(k) Working Group, which was charged with evaluating the 510(k) program, identifying current challenges, and finding opportunities for

improvement. One key recommendation from this report was for CDRH to update the existing 510(k)-related guidances and to address issues with the program.

In February 2011, the 510(k) Guidance Working Group was formed and charged with drafting an update to the 510(k) guidances. In working through this task, the working group determined that it was most practical to merge and consolidate the two existing 510(k) guidances into a single, new guidance. In December 2011, the consolidated new guidance was published.

Not surprisingly, this guidance considered a significant amount of feedback and contributions from public stakeholders because of its potential impact. Specifically, since 2009, CDRH solicited and received feedback in the form of official comments that interested stakeholders posted to public dockets in response to the various 510(k) reports. CDRH also received feedback through stakeholder workshops that have been held over the past few years on this topic as well as through a number of informal channels. Because of the cross-cutting nature of this guidance, it has been issued jointly by CDRH and CBER.

The guidance addresses each of the four critical decision points in the substantial equivalence evaluation of a
510(k). Specifically, these points are as follows: First, the selection of a predicate device and in particular, the appropriate use of multiple predicate devices. The guidance also introduces a new term called the "reference device", which I defined earlier. Second, the general principles for determining what is a new intended use. The guidance also discusses the relationship between the intended use and indications for use of a medical device.

Third, the process for determining what are different questions of safety and effectiveness due to differences in technological characteristics between a new device and the predicate device. And finally, the request for performance data, and of note, a discussion of when clinical data are generally needed.

The guidance also proposes a standardized format for the submission of the 510(k) summary, as well as FDA's proposal to more systematically verify the accuracy and completeness of the summary. The latter section of the guidance provides an update to the Special and Abbreviated 510(k) Programs, both of which were originally introduced in the Paradigm Guidance of 1998.

The guidance addresses several other topics related to the 510(k) program.
The guidance updates the substantial equivalence (or SE) Flowchart.
The guidance addresses the various categories of determinations of not substantial equivalence or NSE. And finally, the guidance addresses the eligibility of devices found NSE for the de novo program.

In terms of impact, we anticipate that this guidance will impact manufacturers, consumers, as well as FDA Review Staff.

To the manufacturers, the guidance may impact when a 510(k) is needed, as well as whether the 510(k) may be submitted as a Traditional, Special or Abbreviated.

Additionally, the manufacturers may be impacted by the content and format of the 510(k) summary, and the fact that this summary would be verified by FDA.

To the consumers, the guidance may impact when new medical devices are available. We hope that this guidance serves to provide clarity, consistency, and transparency to this important program area, which we hope results in the availability of safe medical devices to our consumer stakeholders.

And finally, upon issuance in final, our FDA Review Staff would receive education and training so that they may accurately and consistently implement the principles described in the guidance.

This draft guidance proposes to update our existing policy on the 510(k) Program. Nevertheless, some aspects of the draft guidance do not intend to change this policy. So what is the same? The decision-making points of the 510(k) Flowchart are the same.

The existence and use of the three main 510(k) Programs, that is, the Traditional, Special, and Abbreviated is unchanged. And finally, no change has been proposed or made with respect to the Statute and Regulations that pertain to the 510(k) Program.

So what has changed in terms of this guidance? First, the guidance updates the wording and flow of the 510(k) Flowchart. Second, the use of a template structure for the 510(k) Summary is introduced. Third, the guidance proposes that the 510(k) Summary be verified by FDA. And finally, the guidance updates the eligibility criteria for a Special 510(k).

With respect to the flowchart, the existing and proposed Substantial Equivalence flowcharts feature a number of similarities. Both flowcharts ask for the identification of a predicate device and comparison to a new device. Next, both flowcharts ask whether the intended use of the new device and predicate device is the same.

Third, both flowcharts ask the question, "Do the new and predicate devices have the same technological characteristics?" Both flowcharts request the review of scientific methods for evaluation of new or difference technological characteristics. And finally, both flowcharts involve the evaluation of data and, if provided, whether the data demonstrate substantial equivalence.

Nevertheless, the current and proposed flowcharts do include several clarifications. For example, with respect to the intended use or indications for use, the current flowchart specifically asks if the new device has the same indication statement as the predicate device. In contrast, the proposed flowchart asks about the intended use, which encompasses the indications for use.

The proposed flowchart provides other clarifications. For example, it specifies that all labeling be reviewed to ensure consistency of the indications for use statement, and a high level review of the relevant data sources be performed.

The flowchart clarifies when FDA proceeds with the review of the technological characteristics of the new device and when FDA proceeds with the review of performance data.

The proposed flowchart asks if the new and predicate devices have different questions of safety and effectiveness, whereas the current flowchart refers to new types of safety and effectiveness questions. This clarification was pecifically made to more accurately reflect the language in the Statute. The current flowchart asks if scientific methods exist, whereas the proposed flowchart asks if the identified scientific methods are acceptable.

In conclusion, this draft 510(k) guidance reflects a culmination of a significant multi-year effort with feedback that was received from a wide range of internal and external stakeholders. The draft guidance represents the keystone updated policy on the 510(k) Program, and was issued during a period of time in which FDA is issuing a number of far-reaching policies. FDA specifically encourages all interested stakeholders to review this draft guidance, and to provide us with comments, feedback, questions, concerns, and your suggestions.

Regarding next steps, the draft guidance is open for an official comment period of 90 days, during which feedback is sought from all stakeholders. Upon closure of the comment period, FDA will address all comments received, will make any necessary revisions, and will move to finalize the guidance document. FDA will also develop training for FDA staff and other stakeholders on the use of this guidance.

For assistance in the interpretation of this guidance document, please contact Dr. Joni Foy, the Deputy Director of the Office of Device Evaluation in CDRH. Dr. Foy may be reached via her email address at: jonette.foy@fda.hhs.gov.

We thank you for participating in this CDRH Learn Module, and encourage you to explore other modules that you can find at the link on this slide.
Thank you for your attention.