Guidance for Industry and FDA Staff

Premarket Notification [510(k)] Submissions for Chemical Indicators

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Infection Control Devices Branch
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Office of Device Evaluation

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No.02D-0525. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Table of Contents

I. INTRODUCTION 1

II. BACKGROUND 2

A. SCOPE 2
B. EXCLUSIONS 3
C. DEFINITIONS 3

III. DEVICE COMPARISON 5

IV. DEVICE DESCRIPTION 6

V. INTENDED USE 7

A. PROCESS INDICATOR 7
B. CHEMICAL INTEGRATORS 7
C. AIR REMOVAL INDICATORS 7

VI. FDA-RECOGNIZED STANDARDS 7

VII. PERFORMANCE CHARACTERISTICS 8

A. PROCESS INDICATORS 9
B. CHEMICAL INTEGRATORS 10
C. CHEMICAL INTEGRATOR TEST PACKS 11
D. PROCESS INDICATORS FOR NEW TECHNOLOGY STERILIZERS 11
E. CHEMICAL INTEGRATORS FOR NEW TECHNOLOGY STERILIZERS 12
F. NEW TECHNOLOGY CHEMICAL INTEGRATOR TEST PACKS 12
G. AIR REMOVAL INDICATORS 12

VIII. BIOCOMPATIBILITY 13

IX. ENDPOINT STABILITY FOR CHEMICAL INDICATORS 13

X. SHELF LIFE 13

XI. LABELING 14

XII. REFERENCES 16

XIII. CHEMICAL INDICATOR 510(K) CHECKLIST 17

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Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Premarket Notification [510(k)] Submissions for Chemical Indicators

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

A chemical indicator intended for use in health care facilities to monitor sterilization processes is a class II device as identified in 21 Code of Federal Regulation (CFR) section 880.2800. Chemical indicators are also known as "physical/chemical sterilization process indicators." The term "chemical indicators" used in this document includes process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test Pack.

A person intending to market a chemical indicator to be used in health care facilities must submit to FDA, and have cleared, a premarket notification submission prior to introduction of the device into interstate commerce, in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Regulations governing the general content and format of 510(k) submissions for chemical indicators are codified under 21 CFR Part 807. These and other regulatory requirements pertaining to the marketing of a new medical device are discussed in guidance documents available from CDRH, Division of Small Manufacturers, International, and Consumer Assistance (DSMICA). These requirements are also explained on the Internet in CDRH Device Advice, http://www.fda.gov/cdrh/devadvice/ .

Management of current sterilization technologies requires the use of more than one type of monitoring procedure. Chemical indicators are an integral part of this monitoring process. Along with biological indicators and mechanical monitors, they can provide an effective program to detect sterilization process failures. As part of a complete quality control program, they can help guard against problems associated with user error, sterilizer

malfunction or inadequate sterilant penetration. The adequate performance of sterilizers in health care facilities is important to prevent nosocomial infections. Chemical indicators can provide health care facilities with information on the effectiveness of a sterilization process.

FDA recognizes the importance of providing submitters and other interested parties with the Agency's recommendations for chemical indicators in order to facilitate the assembly of data to maintain consistency of review, and to provide for a more efficient regulatory process. This guidance is intended to provide specific recommendations to 510(k) submitters about information that they should include in 510(k)s for chemical indicators used in health care facilities.

This guidance replaces the draft document entitled, "Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA," which was made available on January 27, 2003. There have been no major changes from the previous draft version.

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 guidances means that something is suggested or recommended, but not required.

Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf .

II. Background

A. Scope

This document provides guidance concerning the content and format of 510(k) submissions for chemical indicators intended to monitor sterilization processes in health care facilities. Chemical indicators for use in health care facilities are class II devices. The product code is JOJ. Section 21 CFR 880.2800 (b), Physical/chemical sterilization process indicator identifies these devices as:

> A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization conditions as measured by these parameters is indicated by a visible change in the device.

FDA has cleared, through the 510(k) process, the following three types of chemical indicators for use in health care facilities:[1]

- process indicators
- chemical integrators
- air removal indicators for test packs.

Therefore, this guidance addresses only these three types of chemical indicators.

The FDA encourages you, the 510(k) submitter, to contact DSMICA or the Infection Control Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, Office of Device Evaluation, if you have any questions before submitting a 510(k) for chemical indicators.

B. Exclusions

This document does not cover the following chemical indicators and indicator related products:

- chemical indicators intended to be used with liquid chemical sterilants[2]
- chemical indicators intended for use in a manufacturing setting
- chemical indicators used for radiation sterilization.

C. Definitions

The following are definitions of terms used throughout the document. Many of the definitions have been standardized by organizations such as the International

[1] These devices react physically or chemically during sterilization. For purposes of being consistent with terminology used in consensus standards, we refer to them as chemical indicators throughout this document.

[2] For these devices, please refer to Guidance for Industry and FDA Reviewers – Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, Section III.K. at http://www.fda.gov/cdrh/ode/397.html.

Organization for Standardization (ISO), the American National Standards Institute (ANSI), and the Association for the Advancement of Medical Instrumentation (AAMI). The standards cited for each definition are cited in full in **XII. References**.

Air Removal Indicator: A chemical indicator to be used in the standard test pack to determine the efficacy of the air removal phase in the steam sterilization process. (ANSI/AAMI, 1999)

Biological Indicator: Microbiological test system providing a defined resistance to a specified sterilization process. (ANSI/AAMI/ISO, 2002)

Bowie Dick Test: A diagnostic test of a dynamic-air-removal steam sterilizer's ability to remove air from the chamber and prevent air re-entrainment. (ANSI/AAMI, 2002)

Chemical Indicator: System that reveals change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process. (ANSI/AAMI/ISO, 2002)

Chemical Integrator: A chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles. (ANSI/AAMI, 1996)

Critical Parameters: Parameters identified as being essential to the sterilization process. (ANSI/AAMI, 1996)

D-Value: The time or radiation dose required to achieve inactivation of 90% of a population of the test microorganism under stated exposure conditions.[3] (ANSI/AAMI/ISO, 2002)

Endpoint: The observable change specified by the manufacturer that occurs after the chemical indicator has been exposed to certain predefined physical conditions. (ANSI/AAMI, 1996)

Indicator Agent: An active ingredient or combination of ingredients that is contained in a chemical indicator. (ANSI/AAMI, 1996)

Medical Device: As defined in the Act (21 USC §321(h)):

> [a]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or

[3] This is the definition for D-value in the standard cited. However, radiation sterilization is not discussed in this guidance document because it is not a sterilization method generally used in health care facilities.

related article, including any component, part, or accessory, which is

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

3. intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Process Challenge Device (PCD): Item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process, and used to assess the effective performance of the process. (ANSI/AAMI/ISO, 2002)

Process Indicator: A chemical indicator that is intended for use with individual units, (e.g., packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. (ANSI/AAMI, 1996)

Resistometer: A test instrument designed to rapidly produce and precisely control critical parameters associated with a given sterilization process. Notes: 1) In addition to routine quality system testing of indicator performance consistency, it is used to characterize cause and effect relationships associated with the given sterilization process and devices used to evaluate the efficacy of the sterilization process, and 2) Resistometers were formerly referred to as a Biological Indicator Evaluator Resistometers (BIER) or Chemical Indicator Evaluator Resistometer (CIER) test systems. (ANSI/AAMI, 2002)

III. Device Comparison

FDA recommends that you include a section or table comparing the new device to the legally marketed predicate device. The following table is an example of the type of information that you should provide.

Table 1- Comparison of the New Device to the Predicate

ELEMENT	NEW DEVICE	PREDICATE
Intended use, e.g., process indicator, chemical integrator, Bowie Dick Test		
Device design		
Indicator agent		
Sterilization method and cycles		
Endpoint specifications		
Shelf-life		

IV. Device Description

You should provide a detailed description of your chemical indicator. The description for your chemical indicator should include the general characteristics regarding the device design and manufacturing specifications. The bulleted list below is an example of the type of information that you should provide in the description for your device. We may request additional information, if the differences in design, formulation, or performance warrant.

- chemical name of indicator agent, e.g., ink, dye, chemical reagent
- chemical composition or formulation of the indicator
- reaction that takes place to achieve its intended endpoint
- sterilization cycles for which the chemical indicator is intended
- critical parameters that the indicator is intended to monitor
- minimum exposure parameters to achieve the endpoint
- recommended storage conditions
- any interfering substances or conditions
- stability of the endpoint reaction, e.g., the stability of the endpoint color
- shelf life

V. Intended Use

You should clearly state the intended use of the chemical indicator. The following are examples of intended use for each type of indicator.

A. Process indicator

The process indicator is intended to be used by a health care provider with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units.

B. Chemical Integrators

The chemical integrator is intended to be used by a health care provider to demonstrate that the parameters over a specified range of sterilization cycles have been met in a specified sterilization wrap, container, cassette, or pouch.

C. Air Removal Indicators

The air removal indicator is intended to be used by a health care provider in a standardized test pack, e.g., Bowie Dick Test Pack, to assess the ability of a prevacuum sterilizer to remove air and allow steam to penetrate into wrapped goods and porous loads. The test pack is usually positioned over the chamber drain in an otherwise empty chamber. An inefficient air removal stage, an air leak, or non-condensable gases in the steam supply are some of the conditions that could cause an incomplete change in the air removal indicator, e.g., uneven color change. The Bowie Dick Test is not an indication that the sterilizer has reached the parameters for sterilization.

VI. FDA-Recognized Standards

If any part of the device design or testing relies on an FDA-recognized standard, you may submit (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard in lieu of data.[4] Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (Section 514(c)(1)(B) of the act). For more information, refer to the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

Recognized standards that apply to chemical indicators are discussed in the following sections.

[4] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

VII. Performance Characteristics

You should provide sufficient information to allow FDA to evaluate the endpoint specifications and performance of the chemical indicator. In order to provide the user with adequate instructions for use, there should be a high visual contrast between the initial and endpoint appearance or physical/chemical change that takes place after processing the chemical indicator, e.g., colors change.

You should provide the critical parameters to which the chemical indicator is intended to respond. For the traditional sterilization processes that are generally used in the health care facility, ANSI/AAMI ST 60 (see **XII. References**) specifies the parameters shown in Table 2 as critical.

Table 2 – Critical Parameters of Traditional Sterilization Processes

STERILIZATION PROCESS	CRITICAL PARAMETERS[a]
Steam	Time, temperature, saturated steam
Dry Heat	Time, temperature
Ethylene Oxide (EO)	Time, temperature, humidity, and EO concentration

[a]The critical parameters not normally tested for chemical indicators are steam quality or degree of saturated steam in a steam sterilization process and relative humidity in an EO sterilization process. The performance of the chemical indicator is evaluated while controlling these critical parameters under specified conditions. These specified conditions are called limiting values. The limiting values for saturated steam, referred to as dryness values, are 0.85 –1.0. The limiting value for EO relative humidity is greater than 30%.

FDA recommends that you provide the following information in your 510(k):

- clear statement of the study objective(s)
- description of the sterilization process used in health care facility for which the indicator is intended, e.g., steam, EO
- description of the health care facility sterilization cycle for which the indicator is intended, e.g., gravity cycle for 15 minutes at 121°C
- critical parameters to which the indicator responds
- specifications for the pass/fail criteria
- pass/fail results obtained from a resistometer
- pass/fail results from an actual sterilization cycle used in a health care facility
- information on the resistance of the biological indicator used in the parallel study, if applicable

- information showing that you used a statistically valid sample size, e.g., 3 lots from 3 different manufacturing runs (i.e., one lot from each manufacturing run)
- description of the positive and negative controls
- conclusion drawn from study.

If feasible, you should also provide actual samples of unprocessed and processed indicators.

A. Process Indicators

You should provide the following information for process indicators.

To characterize the process indicator and demonstrate substantial equivalence, you should provide pass/fail results demonstrating how the indicator reacts to the critical parameters in a resistometer. FDA recommends that the resistometer used for chemical indicator performance testing meet ANSI/AAMI ST 44 (see **XII. References**).

FDA also recommends that the submission include pass/fail results showing how the process indicator would react in an actual sterilizer used in a health care facility. These results should be compared to the resistometer vessel results. If there is a discrepancy between the resistometer and health care facility sterilizer results, you should provide this information in the labeling.

Steam Process Indicators

You should demonstrate, as specified in ANSI/AAMI ST 60, that the chemical indicator does not reach its endpoint when exposed to dry heat at 140°C for 30 minutes.

EO process indicators

You should evaluate EO process indicators as specified in ANSI/AAMI ST 60 to show that after being exposed to 60°C±2°C at greater than 85% relative humidity for not less than 90 minutes, the indicator does not reach its endpoint. This test is done without EO present.

The following table provides the criteria that a process indicator should meet according to the consensus standard ANSI/AAMI ST 60 for the indicated sterilization methods.

Table 3 - Process Indicators Criteria

METHOD	TEMPERATURE	GAS CONCENTRATION	ENDPOINT REACTION
Steam	121°C	N/A	2 min - 10 min
Steam	132°C – 135°C±3°C	N/A	20 sec - 2 min
EO	30°C ±1°C	600±30 mg/l	5 min - 10 min
Dry Heat	160°C ±5°C	N/A	20 min - 40 min

B. Chemical Integrators

The testing described in **Section VII. Performance Characteristics** and **VII. A. Process Indicators** also applies to chemical integrators, with the exception of the performance criteria shown in Table 3. There are no specific performance criteria established for chemical integrators in any published consensus standard. You should provide the specifications for the endpoint reaction for each critical parameter identified and provide the following pass/fail results to support the specifications.

Critical Parameters

You should describe the pass/fail criteria for each critical cycle parameter and provide the pass/fail results to show how the chemical integrator reacts to all the critical parameters in the sterilization cycle for which it is intended. We recommend that you evaluate one parameter at a time in a resistometer while holding the other parameter or parameters constant. The reproducibility of the endpoint reaction should be within the 15% tolerance level of the stated value, as specified in ANSI/AAMI ST 60.

Side-by-Side Testing with the Biological Indicator

You should conduct side-by-side testing of the biological indicator and the subject chemical integrator in an appropriate resistometer. You should use a biological indicator in the study that is legally marketed for the intended sterilization process and cycles. You should also state the D-value for the biological indicator used in the study. The chemical integrator should parallel the performance of an appropriate biological indicator. The results of this study should demonstrate that the integrator does not reach its endpoint before the biological indicator is inactivated, as specified in ANSI/AAMI ST 60.

C. Chemical Integrator Test Packs

Chemical integrators may be used in test packs to simulate products being sterilized.[5] These test packs are intended to create a challenge to the sterilization process that is equal to or greater than the most difficult item routinely processed.

For chemical integrator test packs, you should provide the following information:

- pass/fail results comparing the performance of the chemical integrator in the test pack to the AAMI reference biological indicator test packs in their respective processes (The AAMI standardized test packs are considered the "gold" standards.)
- information to show that the integrator test pack provides an equivalent or greater challenge than the AAMI standardized test pack
- additional information to show that the integrator test pack provides a greater challenge to the process than the integrator by itself.

D. Process Indicators for New Technology Sterilizers

There are no specific performance criteria for chemical indicators for use with new technology sterilizers; however, we believe that the criteria outlined above can be used to evaluate the performance of these chemical indicators. Chemical indicators intended to monitor new technology sterilizers, e.g., vaporized hydrogen peroxide, microwave, gas plasma, ozone, may be determined substantially equivalent to any legally marketed chemical indicator, including a pre-amendments chemical indicator or a chemical indicator found substantially equivalent through the 510(k) process. You should provide pass/fail results characterizing your chemical indicator according to its indications. In general, you should:

- identify the critical parameters of the sterilization cycle, e.g., temperature, time, sterilant concentration
- identify the minimum exposure parameters needed to affect the change of the indicator
- establish the pass/fail criteria
- describe in detail the endpoint reaction or change that is intended to occur
- provide pass/fail results demonstrating how the chemical indicator reacts to the critical parameters specified in an appropriate resistometer vessel, if available, for characterization and compare it to the results obtained above
- demonstrate reproducibility using a statistically valid number of samples.

[5] These test packs are also called process challenge devices (PCDs).

E. Chemical Integrators for New Technology Sterilizers

The testing described in sections **VII. B. Chemical Integrators** and **VII. D. Process Indicators for New Technology Sterilizers** also applies to new technology sterilizer integrators.

In addition, FDA recommends that the biological indicator used to validate the new technology sterilizer cycle also be used to validate the performance of the chemical integrator. The integrator should not reach its endpoint before the biological indicator is inactivated.

F. New Technology Chemical Integrator Test Packs

For new technology integrator test packs, there are no "gold" standards. We recommend that you use the performance criteria for traditional sterilization methods to demonstrate the resistance of the new technology chemical integrator. These performance criteria are identified in ANSI/AAMI ST 46 and ST 41 (see **XII. References**). You should provide pass/fail results demonstrating that the test pack provides a greater challenge to the process than the biological indicator that was used to validate the new technology sterilization process and the integrator itself. For example, the challenge should be equivalent to the increase in the D-value that is provided by the ANSI/AAMI ST 46 and ST 41 standard biological indicator test packs in their respective processes.

G. Air Removal Indicators

For air removal indicators, FDA recommends that you determine the following performance criteria and endpoint specifications inside a test pack (Bowie Dick Test).

You should provide pass/fail results demonstrating that the indicator does not reach its endpoint when exposed to dry heat at 140±2°C for 30 minutes.

You should also provide pass/fail results demonstrating the tolerances for the detection of air in a prevacuum sterilizer. You can simulate this fault condition by injecting air or by not pulling a complete vacuum to produce a non-uniform change in the indicator agent. You should include a thermocouple graph showing the decrease in temperature during the fault condition at the different locations in the cycle.

The thermocouple graph demonstrating a failed result should be compared to the graph showing that the indicator passed. As specified in ANSI/AAMI ST 66, the test temperature within the test pack should be less than 0.5°C for a pass.

For greater sensitivity in detecting air over a larger area, FDA recommends that the air removal indicator sheet in the test pack measure approximately 8 inches by 10 inches (ANSI/AAMI ST 60). The indicator agent should cover a large percentage of the test sheet and it should be uniform.

You should provide specification for the porosity of the material used to construct the air removal indicator. The standard, ANSI/AAMI ST 66 (see **XII. References**) recommends using a standard densitometer to measure the time required for a given volume of air (25ml to 300ml) to flow through a standard area of the indicator being tested to measure the porosity of the test material.

VIII. Biocompatibility

There is the possibility that an active ingredient in some chemical indicators may leach onto the surgical instruments when it comes in contact. You should address this concern by demonstrating that your chemical indicator does not release any substance known to be toxic in sufficient quantities to cause a health hazard or deleterious effect to the user or the devices that are sterilized.

IX. Endpoint Stability for Chemical Indicators

You should demonstrate the stability of the specified endpoint reaction (e.g., color stability) for the chemical indicator at the end of its shelf life.

X. Shelf Life

You should demonstrate that the specification for the endpoint reaction of the chemical indicator is maintained throughout its labeled shelf life. For all studies, you should test at least 3 lots of the production chemical indicators using a sample size that is statistically significant. You should use storage conditions described in the device labeling.

You should provide the following information about shelf life:

- labeled shelf life of the chemical indicator
- dates and length of time for each testing interval, e.g., 0, 6 months, 1 year, 2 years
- resistometer vessel data for each testing interval that demonstrates that the established endpoints are maintained.

Chemical indicators may be unstable at elevated temperatures; therefore, accelerated aging studies may be inappropriate and are not recommended.

In lieu of complete real time shelf life data, the FDA will consider preliminary real time shelf life data (e.g., 6 months) along with a detailed protocol and sampling plan for an ongoing real time (e.g., 2 years) study that you will continue after your device is cleared. These study protocols should include the shelf life information listed above. We also recommend that

you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).

XI. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).[6]

FDA suggests that you provide in the labeling:

- performance characteristics, so that users can determine whether your indicator will meet their needs
- any interfering substances or conditions known to affect the performance of the indicator
- clear description of the physical change that is designed to occur, with descriptions of the indicator both before and after the change, if applicable
- any intermediate changes between the initial and endpoint appearance
- adequate directions for interpretation of the endpoint results or provide a mechanism by which a clearly defined endpoint can be determined by the user, if the endpoint is not clearly obvious
- storage conditions
- expiration date of the unused indicator under specific storage conditions
- any safety precautions required during use
- stability of the endpoint color reaction
- the minimum exposure parameters necessary to affect the change (for chemical integrators only)

In addition to the above, labeling for a Bowie Dick Test Pack should contain the following:

- statement indicating that the device is for use in determining air removal

[6] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. Labeling recommendations in this guidance are consistent with the requirements of part 801.

- warning indicating that extending the manufacturer's recommended time for the Bowie Dick Test may result in false endpoints developing because entrapped air diffuses over time

- warning indicating that Bowie Dick Test should be performed in an empty chamber.

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XII. References

ANSI/AAMI ST 41:1992, Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance

ANSI/AAMI ST 44:2002, Resistometers for Characterizing the Performance of Biological and Chemical Indicators

ANSI/AAMI ST 46:1993, Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance

ANSI/AAMI ST 60:1996, Sterilization of Health Care Products - Chemical Indicators, Part 1: General Requirements

ANSI/AAMI ST 66:1999, Sterilization of Health Care Products – Chemical Indicators – Part 2: Class 2 Indicators for Air Removal Test

ANSI/AAMI/ISO TIR 11139:2002, Sterilization of Health Care Products - Vocabulary

FDA: "Labeling: Regulatory Requirements for Medical Devices" (HHS Publication FDA 89-4203) Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1989 (http://www.fda.gov/cdrh/dsma/470.pdf).

XIII. Chemical Indicator 510(k) Checklist

Yes	No	N/A	Item
			510(k) Summary or Statement
			Indication for Use Statement
			Truthful and Accurate Statement
			Comparison of new chemical indicator to the predicate
			Description
			Formulation of indicator ink
			Chemical reaction with sterilant
			Design description and type of indicator, e.g., process, integrator, Bowie Dick
			Critical parameters to which the indicator responds
			Pass/Fail criteria or minimum exposure parameters that effect the change
			Performance
			Data supporting endpoints with pass/fail criteria
			Data supporting integrator parameters
			Additional data for the Bowie Dick Test
			Data demonstrating tolerance for detection of air
			Porosity of paper carrier
			Biocompatibility information
			Data supporting shelf-life
			Data supporting endpoint color stability
			Labeling
			Name and address of manufacturer
			Intended use including the sterilization process and cycles
			Adequate directions for use
			A clear description of the change that is designed to occur (for color changes examples of the color both before and after the change)
			The storage conditions both before and after use
			Expiration date of the unused indicator under specific storage conditions
			Lot number or other identifiers
			Any safe precautions required during use
			Stability of the endpoint color change
			For integrators, the minimum exposure parameters necessary to effect the change
			Labeling for a Bowie Dick Test should also include:
			Statement indicating that the device is for use in determining air removal
			Warning indicating that extending the manufacturer's recommended time for the Bowie Dick Test may result in false endpoints because entrapped air diffuses over time
			Warning indicating that the Bowie Dick Test should be performed in an empty chamber