Guidance for Industry and FDA Reviewers/Staff

Neonatal and Neonatal Transport Incubators - Premarket Notifications

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U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

General Hospital Devices Branch
Division of Dental, Infection Control, and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Patricia Cricenti, Chief, Division of Dental, Infection Control, and General Hospital Devices, Office of Device Evaluation, 9200 Corporate Blvd, HFZ-480, Rockville, MD 20874. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Patricia Cricenti at 301-594-1287.

Additional Copies

World Wide Web/CDRH home page: http://www.fda.gov/cdrh, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2201 when prompted for the document shelf number.

TABLE OF CONTENTS

1.0 INTRODUCTION

The purpose of this document is to provide guidance to the manufacturers of neonatal incubators and neonatal transport incubators on the information desired for a more thorough and consistent preparation of a Premarket Notification submission (510(k)). This guidance document represents the Agency's current thinking on the above. 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 is such approach satisfies the requirements of the applicable statute, regulations, or both.

The development of this document is based on information currently recognized as necessary for a complete and adequate review of these two devices by the General Hospital Devices Branch. The use of this document for the preparation of a 510(k) for neonatal incubators and neonatal transport incubators is not mandatory and its use does not ensure FDA clearance of a device. However, the use of this document will ensure that the basic elements are present to conduct an evaluation of substantial equivalence for the device(s). Certain 510(k) submissions may require additional information not described in this document. This guidance is subject to revision depending upon new technological information and regulatory requirements.

GENERAL INFORMATION

510(k) Summary or Statement. In accordance with the Safe Medical Devices Act of 1990 and 21 CFR Part 807.87(h), the applicant must submit either: (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (i.e., a “510(k) summary”); or (2) a statement that safety and effectiveness information will be made available to interested persons upon request (i.e., a “510(k) statement”). The summary or statement should be clearly identified as a "510(k) summary" or a “510(k) statement”.

Truthful and Accurate Statement. As required by 21 CFR Part 807.870(j), the applicant must also provide a Truthful and Accurate Statement that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

Indications for Use Form. On January 1, 1996, FDA began requiring that all 510(k) submitters provide an “Indications for Use” statement. This statement is to be on a separate page that is clearly labeled as “Indications for Use,” and will include the trade name of the device and the proposed uses for the device.

The New 510(k) Paradigm. On March 19, 1998, new procedures for the submission of 510(k)'s became effective. These procedures are collectively called the “New 510(k) Paradigm.” More information on the New 510(k) Paradigm is available at the following Website address:

http://www.fda.gov/cdrh/ode/parad5l0.pdf

Other documents and guidances which may be useful in the preparation of the 510(k) can be

found on the CDRH home page at **http://www.fda.gov/cdrh** or by telephone at the CDRH Facts on Demand at 800-899-0381.

2.0 DEVICE DEFINITIONS

A **neonatal incubator** is a device with an enclosure intended to contain a baby and having transparent section(s) which allow(s) for viewing of the baby, and provided with means to control the environment of the baby primarily by heated air within the enclosure (21 CFR Part 880.5400).

A **neonatal transport incubator** is a device with an enclosure intended to contain a baby and having transparent section(s) which allow(s) for viewing of the baby, and provided with means to control the environment of the baby primarily by heated air within the enclosure, and suitable for the safe conveyance of the baby (21 CFR Part 880.5410).

Standards

Standards that are recognized by the FDA:

IEC 601-2-19 Amendment I Medical Electrical Equipment - Part 2: Particular Requirements for Safety of Baby Incubators;

IEC 601-2-20 Medical Electrical Equipment - Part 2: Particular Requirements for Safety of Transport Incubators;

ISO 10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

The following draft standards have not been recognized by the FDA but provide useful guidance for these devices:

AAMI 1151-D-1994 Transport Infant Incubator (Draft Standard);

AAMI/CDV-1 II36 1997 Infant Incubator (Draft Standard).

Note: The above standards reference other standards which may not necessarily be recognized by the CDRH.

3.0 PRODUCT DESCRIPTIONS

- Neonatal Incubator and Neonatal Transport Incubator are classified as 21 CFR 880.5400, PROCODE 80 FMZ and 880.5410, PROCODE 80 FPL respectively. The trade name of each device must be clearly identified.

- Submit a detailed description of your product, its intended use(s), and its indication(s) for use.

- Identify a legally marketed device to which substantial equivalence is claimed and provide a comparative analysis (descriptive or tabular) of the similarities and differences of your device to that legally marketed device in terms of intended use, indications for use, design features, technological and mechanical properties, functional specifications, and operational parameters.
- Clearly state whether or not the incubator is intended for the transport of the patient.

4.0 DESIGN AND PERFORMANCE FEATURES

The design and performance features of the neonatal incubator and transport incubators provide the basis for understanding the intended uses and capabilities of the device. Design features address the intended uses of the device to meet the need of the user and the patient, while the performance features ensure that the devices are safe and effective when use in accordance with the directions. The features listed in this section are important in determining whether the neonatal incubator or neonatal transport incubator described in the 510(k) submission is substantially equivalent to a legally marketed device. A complete discussion of many of these features can be found in the standards documents identified in Section 2.0.

Materials of construction
Engineering diagrams
Mode of operations
    Power source
    Heating and cooling mechanism
    Air controlled versus baby controlled
    Supplementary gas connectors
Functionality
    Physical durability and robustness
    Environmental conditions for proper operations
Performance
    Temperature control
        Accuracy
        Rise Time
        Variability
        Undershoot/Overshoot
    Air Flow
        Velocity
        Flow rates
    Supplementary Gas control
        Connectors
        Mixing/Concentrations
    Safety features
        Weight capacity

Electrical
Restraints
Alarms
Fire protection
Sensors
Lockout

5.0 SAFETY AND EFFECTIVENESS TESTING

A. BIOCOMPATIBILITY OF MATERIALS

Biocompatibility testing is required for all parts of the device that have direct or indirect contact the patient and is performed to determine the potential toxicity that can result from contact of the component materials of the device with the patient's body. The materials used in the construction of the device should not, either directly or indirectly through the release of their material constituents, (1) produce unreasonable risk of adverse local or systemic effects; (2) be carcinogenic; or (3) cause adverse reproductive and developmental effects. The evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by device materials.

Biocompatibility testing is indicated when a "new" or nonconventional material or chemical component is incorporated into a device and there is no known appropriate predicate use or for which the safety or effectiveness of the resulting formulation is in question. These materials or chemical components include plastics, metals, colorants, plasticizers, germicides, and chemical or other treatments of the device or device components. Biocompatibility testing should be performed on the finished product, using test conditions simulating as closely as possible actual patient use. Materials and chemical components that have already been incorporated in legally marketed devices with similar conditions of use, or have a demonstrated history of safety and effectiveness may not require biocompatibility testing; however, the biocompatibility of these materials and chemical components should be fully discussed to support the lack of testing.

Refer to ISO-10993-1:1992, Part I "Biological Evaluation of Medical Devices, Evaluation and Testing", and the FDA-modified Matrix to identify the types of biocompatibility testing that should be considered in evaluating the safety-in-use of medical devices and materials. The ISO Standard, Part 1, uses an approach to test selection that is very similar to the Tripartite Guidance. It also uses a tabular format (matrix) for laying out the test requirements based on the various factors discussed above. The matrix consists of two tables, "Initial Evaluation Tests for Consideration" and "Supplementary Evaluation Tests for Consideration." To harmonize biological response testing with the requirements of other countries, FDA will apply the ISO Standard, Part 1, in the review process in lieu of the Tripartite Biocompatibility Guidance.

Reviewers in the Office of Device Evaluation will accept data developed according to ISO-10993-1: 1992, Part 1, with the matrix as modified and presented in Blue Book Memorandum #G95-1 entitled "Use of International Standard ISO-10993, Biological Evaluation of Medical

Devices Part-1: Evaluation and Testing." The manufacturer also has the option of providing a summary of the specific tests conducted in accordance with the standard.

All testing performed should either be in compliance with the recommended standard documents or be accompanied by an explanation as to how the testing or methodology is an acceptable alternative to that of the standard. Manufacturers are advised to initiate discussions with the General Hospital Devices Branch prior to the initiation of expensive, long-term testing of any new device materials to ensure that the proper testing will be conducted and unnecessary testing will not be undertaken. We also recognize that an ISO standard is a document that undergoes periodic review and is subject to revision. FDA will notify manufacturers of any future revisions to the ISO standards which are referenced in this document.

B. DEVICE PERFORMANCE

The submission would normally contain data to support the safe and effective operations of the device when used according to the directions for use. However, the manufacturer now has the option of providing a declaration of conformance to a standard. A declaration to a standard obviates the need for the submission of protocols and raw data as called for by that standard. If the submission does not include a declaration to a standard, the submission should include performance data from bench testing. Additional data may include results from testing under actual conditions or in a simulated environment in which the device is expected to be used. As with the biocompatibility testing, functional testing should be performed in compliance with the recommended standards or be accompanied by a justification that the testing or methodology is an acceptable alternative to that particular standard.

Manufacturers are advised to initiate discussions with the General Hospital Devices Branch prior to the initiation of extensive performance testing to ensure that proper testing will be conducted. We also recognize that standards are documents that undergo periodic review and is subject to revision. FDA will notify manufacturers of any future revisions any of performance standards referenced here.

6.0 LABELING

It is important to the user that the labeling for the neonatal incubator and neonatal transport incubator bear clear, accurate, and complete information for use concerning any relevant indications for use, conditions and limitations of use, hazards, contraindications, and precautions in their use.

The 510(k) should identify and discuss all known situations and events that could cause the device to malfunction or become a hazard to the user or patient when the device is being properly used. The labeling should discuss these situations and hazards in a precaution, warning, or advisory statement as appropriate.

These devices require prescription labeling and must incorporate the following in the label:

"Caution: Federal Law restricts this device to sale by or on the order of a physician."

Provide the proposed package labels and labeling in your 510(k) submissions for neonatal incubators and neonatal transport incubators. Labeling refers to the package label plus other written, printed, or graphic material that accompanies the device or that is placed on either the device or any of its wrappers or containers. Advertising may be considered labeling, especially if it accompanies the device. The labeling must bear adequate directions for use and any warnings needed to ensure the safe use of the device. See sections 201 (k) and (in) and 502(f)(1) and (2) of the Federal Food, Drug, and Cosmetic Act.

If you wish specific advice for your device on the FDA labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Additionally, note the regulation titled "Misbranding by reference to premarket notification" (21 CFR Part 807.97).