models selected by the Department, or a combination of the foregoing.

(b) *Additional testing requirements*—(1) *Selection of basic models for testing if an AEDM is to be applied.* (i) A manufacturer must select basic models for testing in accordance with the following criteria:

(A) Two of the basic models must be among the five basic models with the highest unit volumes of production by the manufacturer in the prior year, or during the prior 12 calendar months period beginning in 2005,[1] whichever is later;

(B) The basic models should be of different horsepower ratings without duplication;

(C) The basic models should be of different frame number series without duplication; and

(D) Each basic model should have the lowest nominal full load efficiency among the basic models with the same rating (''rating'' as used here has the same meaning as it has in the definition of ''basic model'').

(ii) If it is impossible for a manufacturer to select basic models for testing in accordance with all of these criteria, the criteria shall be given priority in the order in which they are listed. Within the limits imposed by the criteria, basic models shall be selected randomly.

(2) Selection of units for testing within a basic model. For each basic model selected for testing,[2] a sample of units shall be selected at random and tested. The sample shall be comprised of production units of the basic model, or units that are representative of such production units. The sample size shall be no fewer than five units, except when fewer than five units of a basic model would be produced over a reasonable period of time (approximately 180 days). In this case, each unit shall be tested.

Energy Conservation Standard

§ 431.346 Small Electric Motor Energy Conservation Standards and Their Effective Dates. [RESERVED]

13. In § 431.385, paragraph (a) introductory text is revised to read as follows:

§ 431.385 Cessation of distribution of a basic model of an electric motor.

(a) In the event that a model of an electric motor is determined non-compliant by the Department in accordance with § 431.383 or if a manufacturer or private labeler determines a model of an electric motor to be in noncompliance, then the manufacturer or private labeler shall:

* * * * *

[FR Doc. E8–30198 Filed 12–19–08; 8:45 am]

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[1] In identifying these five basic models, any small electric motor that does not comply with § 431.346 shall be excluded from consideration.

[2] Components of similar design may be substituted without requiring additional testing if the represented measures of energy consumption continue to satisfy the applicable sampling provision.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2008–N–0604]

General and Plastic Surgery Devices: Proposed Classification for the Tissue Expander

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify into class II (special controls) the tissue expander, as a device intended for temporary (less than 6 months) subdermal implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance that FDA intends will serve as the special control if FDA classifies this device type into class II.

DATES: Submit written or electronic comments by March 23, 2009. See section IV of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0604, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nada Hanafi, Center for Devices and Radiological Health (HFZ–4), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8848.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), and the Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105–115), the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the agency has taken the following steps:

(1) Receives a recommendation from a device classification panel (an FDA advisory committee);

(2) Publishes the panel's recommendation for comment, along with a proposed regulation classifying the device type; and

(3) Publishes a final regulation classifying the device type.

FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.'' These device types are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those device types remain in class III and require premarket approval, unless and until:

(1) FDA reclassifies the device type into class I or II;

(2) FDA issues an order classifying the device type into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or

(3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval.

The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application (PMA), until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

The tissue expander is a preamendment device type that was not classified in the final rule published in the **Federal Register** of June 24, 1988, classifying other General and Plastic Surgery Devices (53 FR 23856). Consistent with the act and the regulations, FDA consulted with the Panel, an FDA advisory committee, regarding the classification of this device type.

II. Recommendation of the Panel

At a public meeting held on August 25 and 26, 2005, the Panel unanimously recommended that the tissue expander be classified into class II (Ref. 1). The Panel believed that class II, special controls, in addition to general controls, would reasonably assure the safety and effectiveness of this device type. The Panel also recommended that the special control for the device type be a guidance document.

A. Identification

FDA is proposing the following identification based on the Panel's recommendation and the available information: A tissue expander is a device intended for temporary (less than 6 months) subdermal implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. It is made of an inflatable silicone elastomer shell filled with Normal Physiological Saline (injection grade).

B. Recommended Classification of the Panel

The Panel unanimously recommended that the tissue expander be classified into class II. The Panel believed that class II with the special controls (a guidance document and labeling) would provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance that will serve as the special control for this device type.

C. Summary of Reasons for Recommendation

After reviewing the information provided by FDA, and after consideration of the open discussions during the Panel meeting and the Panel members' personal knowledge of and clinical experience with the device system, the Panel provided the following reasons in support of its recommendation to classify the generic device type, tissue expander intended for temporary (less than 6 months) subdermal implantation to develop surgical flaps and additional coverage for surgical applications, into class II. The Panel believed the tissue expander should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide such assurance.

D. Summary of the Data Upon Which the Recommendation is Based

In addition to the potential risks to health associated with implantation of the tissue expander described in section II.E of this document, ''Risks to Health,'' there is reasonable knowledge of the benefits of the device type. Specifically, the tissue expander develops tissue flaps and coverage needed for surgical applications, such as breast reconstruction following mastectomy, treatment of underdeveloped breasts, scar revision, and treatment of soft tissue deformities or injuries.

E. Risks to Health

After considering the Panel's comments and recommendation, the published literature, and medical device reports, FDA has evaluated the risks to health associated with use of the tissue expander. FDA believes the following are risks to health associated with use of the device type:

Skin trauma, including necrosis, thinning and slough;

Device failure, including rupture and injection site/port failure;

Infection—Infection is a risk to health associated with all surgical procedures and implanted devices. Incompatible or impure material composition may irritate the surrounding tissue which could increase the risk of infection. Use of a device that is not pyrogen free may elicit a fever.

Adverse tissue reaction—Adverse tissue reaction is a risk to health common to all implanted devices. The implantation of the tissue expander will elicit a mild inflammatory reaction typical of a normal foreign body response. Incompatible material or impurities in the materials may increase the severity of a local tissue reaction or cause a systemic tissue reaction.

Pain—Pain is a risk to health associated with all surgical procedures and implanted devices.

F. Special Controls

In addition to general controls, FDA believes that the draft guidance document entitled ''Class II Special Controls Guidance: Tissue Expander'' (the draft class II special controls guidance document) is a special control adequate to address the risks to health associated with the use of the device type described in section II.E of this document. FDA believes that the draft class II special controls guidance document addresses the Panel's concerns and provides reasonable assurance of the safety and effectiveness of the device type. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft class II special controls guidance document that the agency would use as the special control for this device type.

The draft class II special controls guidance document sets forth the information FDA recommends submitters include in premarket notification submissions (510(k)s) for a tissue expander. FDA has identified the risks to health associated with the use

of the device type in the first column of table 1 of this document. The recommended mitigation measures identified in the draft class II special controls guidance document is in the second column of table 1 of this document. FDA believes that addressing these risks to health in a 510(k) in the manner identified in the draft class II special controls guidance document, or in an acceptable alternative manner, is necessary to provide reasonable assurance of the safety and effectiveness of the device type.

TABLE 1.—RISKS TO HEALTH AND MITIGATION MEASURES

Identified Risk	Recommended Mitigation Measures
Skin trauma (e.g., necrosis, thinning, sloughing).	Labeling
Device failure (e.g., rupture, injection site/port failure).	Preclinical testing Labeling
Infection	Sterility
Adverse tissue reaction.	Biocompatibility
Pain	Labeling

III. Proposed Classification

FDA concurs with the Panel's recommendation that a tissue expander should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

IV. Proposed Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of this device type into class II will have a negligible impact on manufacturers because manufacturers of the device type currently must provide premarket notification before marketing the device and because FDA believes that manufacturers are already substantially in compliance with the recommendations in the draft guidance document. Because classification into class II will not increase regulatory costs with respect to this device type, the agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain State requirements ''different or in addition to'' certain federal requirements applicable to devices (21 U.S.C. 360k; *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S.Ct. 999 (2008)). In this proposed rulemaking, FDA has tentatively determined that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish special controls to provide such assurance. FDA therefore proposes to establish special controls to address the issues of safety or effectiveness identified in the special controls draft guidance document. If this proposed rule is made final, these special controls would create ''requirements'' for specific medical devices under 21 U.S.C. 360k, even though product sponsors would have some flexibility in how they meet those requirements (*Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–42 (9th Cir. 1997)).

In addition, if this rule becomes final, as with any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would be preempted. (See *Geier* v. *American Honda Co.,* 529 U.S. 861 (2000); *English* v. *General Electric Co.,* 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc.,* 373 U.S. 132, 142–43 (1963); *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).)

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required. This proposed rule designates a guidance document as a special control.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Tissue Expander,'' which contains an analysis of the paperwork burden for the draft guidance.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

X. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. General and Plastic Surgery Devices Panel, Transcript, August 25 and 26, 2005, pp. 11 through 58 of the August 26, 2005, transcripts.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 878 as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 3601, 371.

2. Add § 878.3600 to subpart D to read as follows:

§ 878.3600 Tissue expander.

(a) *Identification.* A tissue expander is a device intended for temporary (less than 6 months) subdermal implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. It is made of an inflatable silicone elastomer shell filled with Normal Physiological Saline (injection grade).

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Tissue Expander.'' See § 878.1(e) for availability information of guidance documents.

Dated: December 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30439 Filed 12–19–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 514, 531, 533, 535, 537, 539, 556, 558, 571, 573

RIN 3141–0001

Amendments to Various National Indian Gaming Commission Regulations

AGENCY: National Indian Gaming Commission (NIGC or Commission).

ACTION: Proposed rules.

SUMMARY: The proposed rule modifies various Commission regulations to reduce reporting burdens on tribes, update costs for background investigations, clarify definitions and regulatory intent, and update audit requirements to consolidate and reflect industry standards.

DATES: Submit comments on or before February 5, 2009.

ADDRESSES: Comments can be faxed, mailed, or e-mailed. Mail comments to ''Comments on Administrative Regulations,'' National Indian Gaming Commission, 1441 L St., NW., Washington, DC 20005, Attn: Rebecca Chapman, Office of General Counsel. Comments may be faxed to 202–632–7066 (not a toll-free number). Comments may be sent electronically to *adminregs@nigc.gov*.

FOR FURTHER INFORMATION CONTACT: Rebecca Chapman, Staff Attorney, Office of General Counsel, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

On October 17, 1988, Congress enacted the Indian Gaming Regulatory Act (IGRA or Act), 25 U.S.C. 2701–21, creating the National Indian Gaming Commission (NIGC or Commission) and developing a comprehensive framework for the regulation of gaming on Indian lands. 25 U.S.C. 2702. The NIGC was granted, among other things, regulatory oversight and enforcement authority, including the authority to monitor tribal compliance with IGRA, NIGC regulations, and tribal gaming ordinances.

The Commission has worked under IGRA for almost twenty years, and in 1992, it adopted regulations. 25 U.S.C. 2706(b)(10). To better carry out its statutory duties, the Commission undertakes this collection of minor, miscellaneous regulation changes. The proposed rule will update regulations, and it will streamline and optimize existing procedures.

II. Development of the Proposed Rules Through Written Tribal Consultation

The Commission identified a need for minor changes to various parts of its regulations, and in accordance with its government-to-government consultation policy (69 FR 16,973 (Mar. 31, 2004)), requested input from Indian tribes. On March 26, 2007, the Commission prepared amendments to the regulations and sent a copy to the leaders of all gaming tribes for comment. Fifty-seven tribes provided written comments. The NIGC carefully reviewed all comments, often incorporating suggested changes.

In addition, the NIGC consulted with tribes and their gaming commissions at regional gaming association meetings around the country and at the Washington, DC, headquarters. Since March 26, 2007, the NIGC has held consultations at fifteen regional gaming conferences and consulted with more than 110 tribes when the proposed rule was on the agenda. Other than the previous 57 submissions, no tribes chose to consult or comment further about these miscellaneous regulation changes.

III. Purpose and Scope

The changes in this proposed rule are minor but provide incremental improvements to existing regulations. These changes clarify existing regulations, reduce tribal reporting burdens for fees, update costs for background investigations, and allow tribes to consolidate audits and/or file shortened versions to reduce costs. The proposed rule is discussed below.

A. Definitions

NIGC regulations define ''key employee'' at 25 CFR 502.14. The jobs listed for key employees are, among other things, subject to a background investigation as a condition of licensure. The proposed rule would reflect the common practice of tribes that identify additional employees as key employees subject to background investigations beyond those positions identified in IGRA. NIGC has received no comments on this change.

IGRA and NIGC regulations define ''net revenue'' as ''gross gaming revenues of an Indian gaming operation