

APPENDIX D

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Proposed Rule for Classification of Impression Materials

compatibility, hardness, and resistance to fatigue (mechanical failure due to stress over time) are the most important considerations. These findings are supported by Bodine (Ref. 3) who evaluated the success rate of subperiosteal implants. Bodine concludes that a major cause of subperiosteal implant failure is inflammation due to deterioration of the implant material, a deterioration caused by impurities in that materials. FDA believes that a performance standard for cobalt chrome molybdenum materials used in subperiosteal implants can be established to detail the properties necessary for a safe and effective implant. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, R., "Implantation of Chrome Cobalt Alloy Forms in the Rabbit's Mandible," *Australian Dental Journal*, 14:396, 1969.
2. Muratori, G., "Multi-Type Oral Implantology," The Marino Cantellic Publishing Co., 64:156, June 1973.
3. Bodine, R., "Implant Dentures," *Journal of Prosthetic Dentistry*, 32(2):188-197, August 1974.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the *Federal Register* of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the *Federal Register*.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D

by adding new § 872.3650, to read as follows:

§ 872.3650 Cobalt chrome molybdenum subperiosteal implant material.

(a) *Identification.* Cobalt chrome molybdenum subperiosteal implant material is a device composed of cobalt chrome molybdenum that is used to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device provides support for prostheses, such as dentures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. to 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 80-39672 Filed 12-29-80; 8:45 am]
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21 CFR Part 872

[Docket No. 78N-2890]

Medical Devices; Classification of Impression Materials

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying impression materials into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation

based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7538.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of impression materials:

1. *Identification:* Impression material is a device composed of materials, such as alginate or polysulfide, that are placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device provides models for study and for production of restorative and prosthetic devices, such as gold inlays and dentures.

2. *Recommended classification:* Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. *Summary of reasons for recommendation:* The Panel recommends that impression materials be classified into class II because the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The quality of the materials must also be controlled to prevent trauma to surrounding tissues or an allergic response in the patient. The Panel believes that general controls alone would not provide sufficient control over the characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. *Summary data on which the recommendation is based:* The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on references in the literature that state that impression materials may cause an allergic reaction or trauma to surrounding tissue (Refs. 1 and 2).

5. Risks to health: (a) Adverse tissue reaction: If the materials of the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Tissue trauma: If the material is not of adequate quality, trauma to the patient's oral tissue may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that impression materials be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Kaloyannides, T. M. and D. J. Kapari, "Mixtures of Elastomer Impression Materials: II," *Journal of Dental Research*, 54:493, 1975.
2. Glenwright, H. D., "Bone Regeneration Following Damage by Polysulfide Impression Material," *Journal of Clinical Periodontology*, 2:250-252, 1975.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the *Federal Register* of May 19, 1978 [43 FR 21666, 21667, and 21668] and May 26, 1978 [43 FR 22672 and 22673]. This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the *Federal Register*.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-564 [21 U.S.C. 360c, 371(a)]) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.3660, to read as follows:

§ 872.3660 Impression material.

(a) *Identification.* Impression material is a device composed of materials, such as alginate or polysulfide, that are

placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device provides models for study and for production of restorative and prosthetic devices, such as gold inlays and dentures.

(b) *Classification.* Class II (performance standard).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in bracket in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Date: November 19, 1980.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

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21 CFR PART 872

[Docket No. 78N-2891]

Medical Devices; Classification of Resin Impression Tray Material

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying resin impression tray material into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.
DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the *Federal Register*.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the *Federal Register* provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of resin impression tray material:

1. *Identification:* Resin impression tray material is a device used in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray is not suitable, such as in the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient's teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient's mouth to make an impression, from which a final, more precise, model of the patient's mouth is cast.

2. *Recommended classification:* Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. *Summary of reasons for recommendation:* The Panel recommends that resin impression tray material be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. *Summary of data on which the recommendation is based:* The Panel based its recommendation on the Panel members' personal knowledge of, and