This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Center for Devices and Radiolgical Health's Premarket Notification (510(K) Refuse to Accept Policy

Food and Drug Administration
U.S. Department of Health and Human Services

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PREMARKET NOTIFICATION (510(K)) REFUSE TO ACCEPT POLICY

PURPOSE

The Office of Device Evaluation (ODE) receives approximately 6500 Premarket Notification (510(k)) submissions every year. Many of these submissions are incomplete or grossly inadequate, as they fail to contain the components necessary to allow substantive review of the submission and inappropriately consume Center resources. As a means to employ more effectively the Center's resources, procedures will be implemented to ensure that 510(k)s meet a minimum threshold of acceptability; otherwise the Center will refuse to accept the submissions for substantive review. These procedures will benefit both FDA and submitters.

DISCUSSION

In the past, the Center has accepted all but the most inadequate submissions and has worked with submitters to bring the submissions up to acceptable levels so the 510(k) decision can be made. This is inefficient and wasteful of resources. It is also unfair to those submitters who fulfill their regulatory obligations by submitting complete and well-supported submissions but whose reviews are delayed while incomplete 510(k)s submitted earlier occupy review time. The Center's goal in establishing a Refuse to Accept policy for 510(k) submissions is to improve the use of our review resources by ensuring that they are focused on the review of reasonably complete and well-supported submissions.

For the purpose of discussing this issue, it is critical to distinguish between the completeness of the regulatory submissions and the quality of the studies conducted and data provided in support of the submission. The Refuse to Accept Policy is not intended to mean that the Center should only be expending resources in the review of submissions for devices that may be substantially equivalent to a predicate device. However, after the initial 510(k) review, the Center will often find that additional data or information is necessary before the reviewer can determine whether the device is substantially equivalent or not substantially equivalent. A decision to refuse to accept a 510(k) will be based on omission of clearly necessary information. By establishing a Refuse to Accept policy with criteria that are clear, consistent, and available to submitters, they will know what is expected of them for the particular submission. Submitters will be likely to comply with the established criteria to speed the time to substantive review and regulatory action.

While we can refuse to accept a submission based upon the content requirements in the regulations, this alone will not upgrade the scientific quality of incoming 510(k)s. We must continue to promulgate product specific guidelines or guidance documents. In instances where we have established clear expectations in a guidance document, we can evaluate the quality of a submission against the consideration the submitter has given the scientific/technical issues addressed in the guidance.

A 510(k) documentation form was developed for the review of these submissions. The checklist prompts a reviewer to ask a series of questions that directly relate to the quality of the 510(k) as well as to substantial equivalence. Certain Class I devices have been exempt from 510(k) by regulation. The 510(k) documentation form is designed to uncover if the device is exempt immediately before any significant resources are expended in a scientific review. Likewise, if there is a question as to whether the product that is the subject of the 510(k) is a medical device, this question surfaces early in the review before any scientific resources are used. The form was originally designed to ensure that all reviewers approach their decisions regarding substantial equivalence using uniform criteria. Some of these considerations and others are incorporated into the new Refuse to Accept Checklist.

RECOMMENDATIONS

As a result of the above considerations, the following recommendations are hereby made to establish refuse to accept criteria for 510(k)s:

1. Train personnel in the Refuse to Accept policy. This policy should be applied to all incoming 510(k) submissions before any in-depth scientific reviews are conducted.

2. Implement a checklist approach to the initial review of all 510(k)s. An example of the proposed checklist can be found attached to this document.

3. Guidelines or guidance documents should be developed whenever needs for such are identified. Guidances should provide specific details about what is expected and acceptable for all components of the submissions. Each product specific guidance should include a checklist to be used by a) the submitter in preparing the submission and b) the CDRH reviewer using the Refuse to Accept Policy as an initial evaluation of the submission. Checklists should be prepared for existing guidelines. These checklists and guidance documents should be made available to industry so they are

aware of what is expected of them for each type of submission. This will save time and provide consistency across submissions. Emphasis should also be placed on improved communication with industry.

IMPLEMENTATION

The refuse to accept policy will be implemented by the ODE review divisions as of this date.

1. Processing

   a. The ODE Document Mail Center will log in, jacket, and distribute the 510(k) to the appropriate review division within 5 days or as quickly as available resources allow.

   b. A designated reviewer (Branch Chief, Reviewer, CSO, CST), using the 510(k) Refuse to Accept checklist and other device-appropriate checklists, will determine if the 510(k) submission is complete enough to allow substantive review and make a recommendation within 21 days. The division should consult with POS on any decisions that are particularly difficult or controversial.

   c. Refuse to Accept recommendations will be forwarded to the supervisor for concurrence. If the submission is found sufficiently complete to allow substantive review, a priority for the review also will be recommended.

   d. Upon supervisor's concurrence with the Refuse to Accept recommendation, a refuse to accept letter will be prepared for the division director's signature.

   e. A Refuse to Accept letter, detailing the omissions or inadequacies that lead to the decision not to accept the submission will issue within 30 days of receipt of the original 510(k). The letter will clearly state whether a complete new submission must be provided or will specify which portion of the submission must be provided if the submitter wishes to pursue clearance for marketing. Copies of pertinent guidance documents will be enclosed with the Refuse to Accept letter.

2. Industry Inquiries

In the event that the submitter has questions regarding the Refuse to Accept letter, the submitter may contact the appropriate Division Director, via phone or FAX, regarding the decision.

3. Monitoring

The implementation of the Premarket Notification (510(k)) Refuse to Accept Policy will be reviewed by the Office of the Director, ODE, at 3 month intervals to determine the number of incomplete and/or inadequate submissions not accepted, the consistency with which the criteria are applied, further necessary refinements to the process, and the overall impact on the 510(k) program.

The Center will continue to disseminate written guidance and will communicate with manufacturers to help improve submissions and to help ensure that submissions are complete and reviewable. Nonetheless, we will no longer accept submissions that will not allow us to conduct a substantive review.

EFFECTIVE DATE

The Premarket Notification (510(k)) Refuse to Accept Policy is effective immediately.

CONCURRENCE

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510(k) REFUSE TO ACCEPT CRITERIA

As a means to utilize more effectively review resources and to improve the timeliness of the device evaluation process, the Center is establishing a Refuse to Accept Policy for Premarket Notifications (510(k)s).

In the 510(k) arena, the logical point to make a minimum threshold determination regarding the quality of the submission and whether the submission merits a substantive evaluation by agency scientists is in the immediate post-receipt time-frame.

The Center's Office of Device Evaluation will implement the Refuse to Accept Policy in the review divisions. In general, there are four bases to refuse to accept a Premarket Notification submissions:

1. The product is not a device in accord with the Federal Food, Drug, and Cosmetic Act, Section 201 (h).

2. Premarket notification is not required under 21 CFR 807.

3. The submission omits a critical section of the 510(k) submission required under the implementing regulations or as a matter of policy.

4. The submission fails to address scientific/technical issues clearly described in publicly available general, device-specific, and crosscutting guidance documents.

The attached 510(k) Checklist for Acceptance Decision is intended to accomplish the following: provide uniform guidance as to when a submission should be accepted or not accepted; ensure that regulatory obligations are met; ensure consistency of review among the Divisions; and to upgrade the quality of submissions. It is intended that this checklist will be used to separate out those 510(k)s which are sufficiently complete to permit in-depth scientific reviews from those that are lacking important regulatory elements or are so grossly deficient in a particular element such that, in effect, the element has not been provided. When FDA has provided product specific guidelines or guidance documents to industry, these documents are to be used in conjunction with the 510(k) Checklist for Acceptance Decision. The reviewer should keep in mind that the purpose of this acceptance review is to ensure reviewability, not the substantial equivalence of the 510(k).

There are three parts to the 510(k) Checklist for Acceptance Decision corresponding to the information required for these notifications as specified in the Act or the implementing regulations, in other guidance documents, and the additional information that may be required in a subset of submissions as a matter of policy. Submitters are still expected to submit information as required by the Act, regulations, and as described in the manual Premarket Notification; 510(k) - Regulatory Requirements for Medical Devices. The 510(k) Checklist for Acceptance Decision is an aid to the submitter and the reviewer and is NOT a new 510(k) contents outline.

To use this checklist place a check mark in the "Yes" block (left hand column) when: the item is present and adequate; a justification for an omitted item has been provided; or a waiver has been requested. Place a check in the "No" block (right hand column) when the item is grossly inadequate or omitted without valid justification.

A decision memo must be included with this checklist which provides the rationale for the decision as well as a brief explanation for all "No" answers and any other minor questions included in the decision letter.

The Refuse to Accept letter will be accompanied by a completed "510(k) Checklist for Acceptance Decision", the decision memo, a completed Statistical Checklist (where appropriate), and any product specific guidance or guideline.

REVISED:3/14/95

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K_____ Device Name_____

Division/Branch_____

Administrative Reviewer Signature_____Date_____

Supervisory Signature_____Date_____

Did the firm request expedited review? _____Yes_____No

Did we grant expedited review? _____Yes_____No

Truthful and accurate statement enclosed?_____Yes_____No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

_____ Accepted

_____ Refuse To Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☐	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☐
C. Is Device Subject To Review By CDRH?	☐	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	☐	☐
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐	☐
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer.	☐	☐
(ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	☐	☐

F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	☐	☐
1. Device Trade Or Proprietary Name	☐	☐
2. Device Common Or Usual Name Or Classification Name	☐	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☐	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☐	☐
5. Classification Panel	☐	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☐	☐
8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	☐	☐
9. For Class III Devices Only, A Class III Certification And A Class III Summary	☐	☐
10. Photographs Of The Device	☐	☐
11. Engineering Drawings For The Device With Dimensions And Tolerances	☐	☐
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	☐	☐
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	☐	☐
14. Data To Show Consequences And Effects Of A Modified Device(s)	☐	☐
15. Truthful And Accurate Statement	☐	☐
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	☐	☐
A. Submitter's Name And Address	☐	☐
B. Contact Person, Telephone Number And Fax Number	☐	☐
C. Representative/Consultant If Applicable	☐	☐
D. Table Of Contents With Pagination	☐	☐

E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	☐	☐
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	☐	☐
A. Comparison Table Of The New Device To The Marketed Device(s)	☐	☐
B. Action Taken To Comply With Voluntary Standards	☐	☐
C. Performance Data	☐	☐
MARKETED DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐
Clinical Data	☐	☐
NEW DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐
Clinical Data	☐	☐
D. Sterilization Information	☐	☐
E. Software Information	☐	☐
F. Hardware Information	☐	☐
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	☐	☐
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	☐	☐
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	☐	☐
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	☐	☐
I. Other (Specify)	☐	☐