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.

DRAFT 9/7/92
Date: 9/7/92

GENERAL GUIDANCE DOCUMENT

DEVICE: NON-INVASIVE PULSE OXIMETER

Information in the 510(k) should include the following information:

1. EXECUTIVE SUMMARY

An executive summary which serves as a general description of the oximeter and its indications for use should be included in the premarket notification. This description should indicate if the oximeter is a modified or enhanced version of a legally marketed device, whether it be modifications in hardware, software, features, accessories, components, or intended use. If the device comes in a variety of configurations, sizes, or accessories, or is sold with a variety of other components, every configuration or combination should be clearly identified and pictures should be provided.

2. INTENDED USE:

Please identify the intended function of the oximeter (i.e., monitoring of oxygen saturation levels and pulse rate, secondary monitoring modality for infant apnea monitoring, etc.) the intended environment of use, the intended target patient population (i.e., adult, pediatric, neonatal), and the intended duration of use for the oximeter (i.e., short-term or long-term monitoring, spot checking, etc.). This information should include all indications and claims for the device.

If the device has a new indication statement when compared to the predicate device, do the differences alter the intended therapeutic/diagnostic/etc. effect? The reponse to this question should focus on the impact on safety and effectiveness. Clinical data may be needed to demonstrate that the answer to this question is no for the new indication (See section 2(M)(e). Otherwise, the device may be found to be not substantially equivalent.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: Yes/No

B. Implant (short-term or long-term): No

C. Are the device or transducers sterile? Yes/No
If yes, sterility information should be provided in accordance with the 510(k) Sterility Review Guidance.

D. Are the device or transducers for single use? Yes/No
If the oximeter features both single use, disposable and reuseable transducers, this information must be clearly identified in the submission and labeling. If a transducer is reuseable, the labeling must identify the recommended resterilization procedure, identify the maximum number of resterilization processes to be performed on the transducer, and identify a performance test(s) or inspection(s) that the transducer must meet after each resterilization process. Validation data demonstrating that the resterilization processes do not compromise the function of the transducer is also required for review.

E. Is the device for prescription use? Yes
If yes, prescription labeling must be included in the labeling.

F. Is the device for home use or portable? Yes/No
Whether the answer is yes or no, adequate environmental testing should be conducted on the device. If it is home use or portable, testing should be performed in accordance with the Reviewer Guidance for Home Use Respiratory Devices and the results provided. For other devices, appropriate testing should support its use in its intended environment, with proper reference to industry and/or government standards/guidance used. In all cases, the premarket notification should include testing procedures and protocols, an explanation of how the testing procedures and protocols simulate the intended environment of use, test results, and an analysis of of the results.

G. Does the device contain drug or biological product as a component? No
If yes, consultation from other FDA centers may be required.

H. Is this device a kit? No
If yes, and some or all of the components are not new, the submission should include a certification that these components were either preamendment or were found to be substantially equivalent (provide 510(k) number(s) and proof of preamendment status).

I. Is the device Software-driven? Yes/No
The firm should provide a hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices. The software of a pulse oximeter is a major level of concern. The hazard analysis and the most recent software version should be included in the file.

J. Electrically Operated: Yes/No
If yes, AAMI or IEC allowable leakage current requirements should be met

and information should include the test protocol, data, and results. Electrical safety requirements should also be discussed including applicable standards to which conformance has been demonstrated. This may also include appropriate data (test protocol, data, and results).

K. Applicable standards to which conformance has been demonstrated in addition to those already mentioned: (e.g., IEC, ANSI, ASTM, ETC.):

If standards applicable to the device include testing to demonstrate conformance, test data should be provided to demonstrate conformance (protocol, data, and results).

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status should be provided. For those devices that are preamendment, supporting documentation showing that they were marketed prior to May 28, 1976 may need to be provided.

M. The submission should include comparative specifications: Yes[a]

comparative <u>in vitro</u> testing:	Yes[b]
performance data:	Yes[c]
animal testing:	Yes/No[d]
clinical testing:	Yes[e]
biocompatibility testing:	Yes[f]

a. A comparison of similarities and differences (features, specifications, intended use, materials, design, theory of operation, detection capabilities, accessories, etc.) in tabular form should be included. Differences should be explained with supporting rationale and/or data. If new characteristics (whether technological or intended use) could affect safety or effectiveness, clinical data would be needed to demonstrate that new technological characteristics raise no new issues of safety and effectiveness or that new indications do not impact safety and effectiveness. If reference literature is used to support any differences, copies of the articles must be provided as opposed to listing the author and titles, the significant areas of the articles must be highlighted, and a summary must be provided relating the information to the issue at hand, including a discussion of the study protocol, data, statistical analyses, and a summary of the results. Reference literature would not always be acceptable to justify the differences between a new and predicate device. See item "e" for clinical testing. If the differences include material differences, biocompatibility testing may be required (see item "f" below). Differences may also require other performance data to be submitted to assess the effects of new characteristics. Note that if the device is a modified or enhanced version of a legally marketed device, whether it be modifications in hardware, software, features, accessories,

components, or intended use, the tabular comparison should include this information. Also note that if the device comes in a variety of configurations, sizes, or accessories, or is sold with a variety of other components, every configuration or combination should be included in the comparison and 510(k) numbers or proof of preamendment status for components or accessories should be provided.

b. Comparative bench testing is applicable for demonstrating substantial equivalence to a currently marketed, predicate device. If the oximetry algorithms and accuracies are affected, comparative bench testing is useful in demonstrating substantial equivalence; however, clinical testing supporting the accuracy specifications will also be required (refer to section e). The comparative bench testing should include simulataneous testing of the oximeter under review and the currently marketed, predicate device and should demonstrate that the performance of the oximeter under review is substantially equivalent to that of the predicate device. The information in the premarket notification should include the testing procedures and protocols, test results, and an analysis of the results.

c. Performance data including testing procedures and protocols, test results, and an analysis of the results explaining how testing and data demonstrate that the device performs as intended and within specification should be provided in the premarket notification.

The following are examples of issues or features which would require performance testing with supporting data. When performance testing is submitted in a premarket notification, the information should include testing procedures and protocols, test results, an analysis of the results.

i. With non-invasive pulse oximeters, patient burns caused by incompatible transducers and failure of current limiting safety mechanisms is a safety concern. Several devices feature current limiting curcuitry or safety mechanisms that prevent excessive current from being delivered to the transducer. The premarket notification should provide testing demonstrating the safety and efficacy of these safety mechanims.

ii. Many non-invasive pulse oximeters feature alarming capabilities for low and high oxygen saturation, low and high pulse rate, low battery, etc. Alarm reliability testing information should be provided to demonstrate the safety and efficacy of the alarms.

iii. If the pulse oximeter is intended to be used with an apnea monitor or is intended to function as a secondary monitoring modality for infant apnea monitoring, then performance testing, in accordance with the Draft Proposed Standard For The Infant Apnea Monitor, should be submitted for review.

d. Animal testing including protocol, data, and a summary of the results should be provided, if necessary.

e. Clinical testing should be submitted to support the accuracy specifications issued by the manufacturer. During this testing, the oximeter under review should be used to measure the arterial hemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood samplings with a Co-oximeter. The data should reflect the type of sensors used during the evaluation and address the tolerance of error (accuracy) in the performance specification. Should there be a significant difference between the performance of the sensors, the tolerance of error must be specified accordingly for each sensor type. The submitted data must be statistically valid and reflect the entire target patient population.

Collected data from adult patients is applicable to pediatric patients, but is not applicable for neonates. Clinical data may be derived from healthy adult subjects who were subjected to a progressive induced hypoxia measuring the arterial hemoglobin oxygen saturation values with the pulse oximeter and comparing to those determined from arterial blood samplings, see below information concerning institutional review board (IRB) approval. Clinical data supporting the accuracy specifications for the neonatal patient population should be submitted based on therapeutic necessity as required by medical indications for blood gas analysis requirements in order to optimize the ventulatory therapy of neonates.

Clinical testing information in the premarket notification should include the investigational plan, justification of patient population and number of devices used, data, statistical analyses and the basis for them, and a summary of results. Note that <u>all</u> clinical studies must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812). If the FDA or institutional review board(s) (IRB) at the institution(s) where the study will be conducted considers the device to be one of significant risk, then any clinical study must receive FDA and IRB approval before initiating a clinical study with the device. Otherwise, if the IRB(s) at the institution(s) where the study will be conducted determine that the device is a non-significant risk device, then the study should be conducted

under the auspices of the (IRB) even though an IDE would not need to be filed with the FDA. In the case of a non-significant risk determination, the submission should include documentation from the IRB identifying the determination and the submission should indicate if patient consent was obtained.

f. Biocompatibility testing should be provided for the materials of the oximetry transducers. This bicompatibility information should include the tests identified in the applicable category of the Tripartite Biocompatibility Guidance for Medical Devices. The premarket notification should include the testing procedures and protocols, the pass/fail criteria, the test results, and an analysis of the results.

N. Provide a discussion about the devices design, materials, physical properties, theory of operation, diagnostic/monitoring/therapeutic capabilities, intended uses, etc., and toxicology profile if important.

O. Engineering Drawings/Drawings/Pictures should be provided for the device.

P. All labeling and promotional literature, including packaging, directions for use, operator's and training manual, and advertisements, should be included in the 510(k). The labeling for the device should include the specifications for the device, specifically, the accuracy specifications. If the accuracy specification for oxygen saturation over a given range is claimed to be within 1 standard deviation, then the labeling should define for the user what is meant by 1 standard deviation (i.e., the accuracy of a given oxygen range is valid for only 68% of the data points taken and the remaining 32% of the data points are not accounted in the specification.)

Q. The submission should contain one of the following: a summary of safety and effectiveness information upon which an equivalence determination is based (510(k) summary) or certification that such information will be made available to interested persons upon request (510(k) statement).

R. If the device is a class III device, the submission should include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description.

S. Possible classifications for Non-Invasive Pulse Oximeters:

870.2700 Oximeter	74 DQA	Class II
870.2710 Ear Oximeter	74 DPZ	Class II