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.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: JUN 13 1995

From: Deputy Director for Science and Regulatory Policy, Office of Device Evaluation

Subject: Electromagnetic Compatibility for Medical Devices: Issues and Solutions

To: Scientific Review Staff

On May 24th and 25th, I participated in the FDA/AAMI EMC Conference entitled Electromagnetic Compatibility for Medical Devices: Issues and Solutions. The conference was held in Anaheim, California and was very well attended by experts in the field along with interested persons from academia, government, the device industry and the user community. All in all, it was a very worthwhile conference where issues were discussed and ideas exchanged in a collegial manner.

Personally, the experience was enlightening and I left with a greater appreciation of the fact that EMC is a very complex issue whose resolution depends on a multi-faceted approach involving education and training, standards development, voluntary compliance and premarket testing requirements for select devices. Furthermore, we can impact the current situation sooner and to a greater extent if we can maintain a spirit of cooperation and collaboration among the interested groups.

After listening to the presentations and having discussions with many attendees, it became very apparent that there is tremendous concern and confusion in the community about our office's policy regarding premarket EMC testing requirements for medical devices. Of particular concern is the apparent use of the November 1993 Respiratory Devices Guidance for nonrespiratory devices by some divisions. While I am sure our intent has been to use the November 1993 document as a convenient tool to begin to address EMC, there certainly has been concern raised about the appropriateness of doing so. A number of other inconsistencies in our approach were brought to my attention that I believe require the issuance of interim guidance in this area until such time that the Center's EMC Working Group can provide more detail.

Until further notice, we need to control in a very deliberate manner all further expansion of premarket EMC testing requirements. This is not to say that we cannot impose EMC testing requirements on new devices going to market. Clearly, we have the authority and responsibility so long as it is justified and does not appear to be done in an arbitrary and capricious manner. This means that we need to carefully phase-in new EMC testing requirements after the affected segment of the industry has been involved in their development and been given an opportunity to prepare to meet the new requirements. With EMC being such a pervasive issue affecting many devices currently in use, we need to be very careful not to negatively impact the development of safer and more effective devices strictly because of EMC concerns. Additionally, we need to be careful not to neglect the legally marketed predicate devices that may pose similar EMC concerns that entered the market before our heightened EMC sensitivity.

As an interim measure, I believe that it is rational to limit our premarket EMC testing requirements to those devices where we have a history of requiring EMC data before clearance and the industry is currently aware of our need for the data. Additionally, in the case of new (1st-of-a-kind) electrically

powered devices going through premarket approval, I believe that we should require appropriate preapproval EMC testing. Keep in mind, if we are going to impose testing requirements under these circumstances, we need to be sure that test methods exist and that acceptability of performance can be determined. Likewise, we need to evaluate the appropriateness of alternatives to doing actual testing such as insisting that warning statements or special use instructions appear in device labeling. As you encounter concerns with specific devices, I am requesting that you consult with your division's EMC focal point and justify and document the basis for any further expansion of EMC testing requirements.

While there may be some dissatisfaction with this interim approach to dealing with EMC, I believe that it will afford us an opportunity to work with the industry, as well as the scientific and user communities, to heighten the awareness of EMC concerns in a nonconfrontational manner. We need to take every opportunity to sensitize the device industry, particularly the small manufacturer, to EMC concerns and to encourage the consideration of EMC during the device design phase.

In order to minimize the chance of misinterpretation of this memorandum, I want to emphasize four points that are essential to strategically resolving the EMC dilemma. As an organization, we must:

(1) limit current premarket EMC testing requirements to those devices where we have a history of requiring EMC data before clearance and the industry is currently aware of our need for the data;

(2) carefully phase-in new EMC testing requirements after the affected segment of the industry has been involved in their development and been given an opportunity to prepare to meet the requirements;

(3) be sure that test methods exist and that acceptability of performance can be determined; and

(4) be careful not to neglect the legally marketed predicate devices that may pose similar EMC concerns that entered the market before our heightened EMC sensitivity.

I hope that this interim guidance does not dampen the enthusiasm that I have encountered in tackling the EMC problem. It is intended to simply remind everyone that the true solution lies in a comprehensive strategy that involves more than the Office of Device Evaluation and preclearance testing of new devices.

Thanks in advance for your continuing cooperation in dealing with this very difficult issue.

Philip J. Phillips