NOTE: On October 26, 2002, the President signed the Medical Device User Fee and Modernization Act (MDUFMA) of 2002. Under this new law, you must pay a fee before FDA will review your Premarket Notification 510(k). Please see "Premarket Notification 510(k) Review Fees." http://www.fda.gov/cdrh/devadvice/314a.htmlfor details on submitting user fees.

HHS Publication FDA 95-4158

PREMARKET NOTIFICATION 510(k):

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES

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Division of Small Manufacturers Assistance

Office of Health and Industry Programs

CENTER FOR

DEVICES AND

RADIOLOGICAL HEALTH

CDRH

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Food and Drug Administration Center for Devices and Radiological Health Rockville, Maryland 20850

FOREWORD

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and non-ionizing radiation, and to assure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports disseminate results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

We welcome your comments and requests for further information.

D. Bruce Burlington, M.D.
Director
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PREFACE

The Medical Device Amendments of 1976 mandated the establishment of "an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the Federal Food, Drug, and Cosmetic Act." The Division of Small Manufacturers Assistance (DSMA) in the Office of Health and Industry Programs (OHIP) was established to meet this requirement. DSMA develops educational materials and sponsors workshops and conferences to provide firms with firsthand working knowledge of medical device requirements and compliance policies.

This manual covers premarket notification [510(k)] submission requirements and addresses the basic regulatory requirements that all manufacturers and distributors must consider when they plan to market medical devices, including medical device kits, trays or packs, in the United States.

The DSMA staff and the Office of Device Evaluation (ODE), in the Center for Devices and Radiological Health (CDRH) provided valuable assistance in preparing this manual.

For further information, contact the appropriate office within CDRH or call DSMA at 800-638-2041, 301-443-6597 or FAX 301-443-8818. Comments on this manual, related workshops, and other DSMA activities, are always welcome.

John Stigi
Director
Division of Small Manufacturers Assistance

ABSTRACT

L. Rice and A. Lowery, Project Officers. Division of Small Manufacturers Assistance, Office of Health and Industry Programs. Premarket Notification 510(k): Regulatory Requirements For Medical Devices. HHS Publication FDA 95-4158 (August 1995)(pp. 116).

This manual covers premarket notification [510(k)] requirements for medical devices. It contains guidance of significance to manufacturers and distributors of medical devices. This manual incorporates changes required by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. This manual is an update of HHS publication FDA 92-4158, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices".

This is a manual used in the Division of Small Manufacturers Assistance (DSMA) medical device workshops.

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Other Related Documents ***(updated January 2000)***

1 OVERVIEW OF THE MEDICAL DEVICE REGULATIONS

INTRODUCTION

Products meeting the definition of a device under section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act or "the Act") are regulated by the Food and Drug Administration (FDA).