FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

The United States of America

Section 510(k)

Cleared on June 9, 2004

MIS - IMPLANT TECHNOLOGIES LTD.

K040807

Classification Name: Implant, Endosseous, Root-Form

Regulatory Class: Class III

TRADE NAME

MIS Dental Implant System

Intended Use:

The MIS Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and it has been determined that the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act) that do not require approval of the premarket approval applications (PMA). You may therefore, market the device, subject to the general controls provisions of the Act.