



FDA CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Section 510(k)
Cleared on December 8, 2000

American Dent-All, Inc.

Classification Name:
Non Precious Dental Casting Alloys

Regulatory Class: Class IIa

TRADE NAMES

LITHECAST
SUPERBOND
EVERSOFT
SUPREMCAS V
SUPREMCAS T
FLEXICAST
FLEXICAST PRIME

The
United
States
of
America



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.