DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

Mr. Juan Fernando Salazar
MasterDent, Ltda.
CRA. No. 39 Sur 90
A.A. 52101 Medellin
Envigado, Columbia

Re: K992854
Trade Name: Artificial Teeth (Acrylic Teeth)
Regulatory Class: II
Product Code: ELM
Dated: November 17, 1999
Received: November 30, 1999

Dear Mr. Salazar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K992854/A1

510(k) NUMBER (IF KNOWN): K992854

DEVICE NAME: ARTIFICIAL TEEHT(Acrylic Teeht)

INDICATIONS FOR USE:

ACRYLIC TEEHT ARE USE FOR MAKING,FULL AND PARTIAL DENTURES. THE ACRYLIC TEEHT ARE MOUNTED ON A APPLIANCE,MADE OF DENTAL ACRYLIC. ONCE THAT APPLIANCE IS MADE IS FITTED IN TO PATIENT MOUTH . THIS APPLIANCE IS REMOVABLE ,IS NOT IMPLANTED.

SINCERELY.

Juan Fernando Salazar .

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANO
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992854

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Co
(Optional

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