



NOV 15 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

TÜV America, Incorporated  
C/O Mr. Stefan Preiss  
Responsible Third Party Official  
Dunia Perwira Manufacturing SDN. BHD.  
1775 Old Highway 8  
New Brighton, Minnesota 55112-1891

NOV 21 2005

Re: K053114  
Trade/Device Name: AMALGAM ALLOY- SILVERFIL  
Regulation Number: 872.3050  
Regulation Name: Amalgam Alloy  
Regulatory Class: II  
Product Code: EJJ  
Dated: October 7, 2005  
Received: November 7, 2005

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined 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 a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Chiu Lin", is written over a circular stamp or seal.

Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

# Dunia Perwira Manufacturing Sdn Bhd

SUBJECT:

510(k) Application

Doc. No:

:

DPM-510k-001

Date / Rev.

:

July 19<sup>th</sup> 2005 / 03

## Section E – Statement of Indication for Use

DEVICE NAME: AMALGAM ALLOY – SILVERFIL

### INDICATION FOR USE:

Silverfil amalgam is used by dental professionals to fill tooth cavities. It is used in the same way as other amalgams used in the world today. Its usage and handling techniques are the same as other amalgams.

Prescription Use YES

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number

K053114