

NOV 15 1999

K993344

# ***NORTH AMERICAN ALLOYS, INC.***



225 Brentwood Ct. • Bloomington, IL 60108-2111 • 630-980-5618 Fax 630-980-9556

## 510(k) SUMMARY

**Trade name:** "P10 Special" Alloy

**Common name:** Base Metal Alloy

**Classification name:** Base Metal Alloy (per 21 CFR 872.3710)

**Device Description:** P10 Special alloy is a cobalt based crown and bridge alloy containing chromium and molybdenum.

**Intended use:** The fabrication of a custom crown or bridge prosthesis by a dental laboratory.

**Predicate devices:** Austenal "Advantage", Jeneric "RX Biocast" CMP "Vulcan" are Co-based crown and bridge alloys.

### Summary of Technological Characteristics:

A comparison of compositional analysis indicates P10 Special and the predicate devices to be similar, with a total Co/Cr/Mo sum percentage of 89-94 %.

A comparison of physical properties indicates P10 Special alloy is similar in yield strength to "Advantage". "P10 Special" has a higher yield strength but is not as hard as Vulcan. Vulcan exhibited somewhat higher % elongation.

Performance testing by field laboratories indicated that P10 Special met or exceeded performance standards of traditional crown and bridge alloys being utilized.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kathleen Calero  
President  
North American Alloys, Inc.  
225 Brentwood Ct.  
Bloomington, IL 60108-2111

Re: K993344  
Trade Name: P10 Special  
Regulatory Class: II  
Product Code: EJH  
Dated: September 28, 1999  
Received: October 5, 1999

Dear Ms. Calero:

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

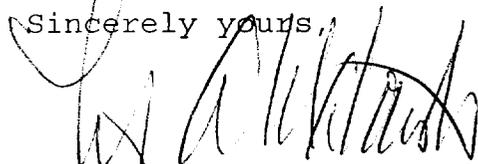
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

K 933344

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510(k) Number (if known): K 993344

Device Name: P10 Special

Indications For Use:

For the fabrication of a custom crown or bridge prosthesis by a dental laboratory. It is to be offered as an alternative to nickel-based crown and bridge alloys for nickel sensitive patients, as well as for international markets which prefer cobalt-based alloys.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR

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

(Optional Format 1-2-96)

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 (Division Sign-Off)   
 Division of Dental, Infection Control,   
 and General Hospital Devices   
 510(k) Number K993344