

APR 21 1997

K970205

**510 (K) Notification Summary**

Attachment # 1

**Pre-market Notification:** K970205  
**Submitter's Name:** Austenal, Inc.  
4101 W. 51st Street  
Chicago, IL.  
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**Contact Person:** Ronald Dudek  
**Date of Filing:** March 31, 1997  
**Trade Names of Alloy:**

Signature: \_\_\_\_\_

*Ronald Dudek*

- 1) Vitallium 2000 Alloy
- 2) Vitallium 2000 Plus Alloy
- 3) Cobalt Chrome Casting Alloy

The above name products are intended for use as base metal casting alloys for casting removable partial denture frameworks. These products are part of a class of materials called base metal casting alloys. Substantially, equivalent products for these products are preamendment devices Vitallium Alloy, Vitallium 2 Alloy, and Vitallium Equipoise Alloy cover by 510 (K) Notification K 880875.

Vitallium 2000 Alloy, Vitallium 2000 Plus Alloy, Cobalt Chrome Casting Alloy, and the predicate products comply with the compositional and mechanical property requirements of ISO Product Standard: ISO 6871, Base Metal Casting Alloys- Part I Cobalt Based Alloys and ANSI/ADA Standard Specification ANSI/ADA # 14 Base Metal Casting Alloys.

**Composition Requirements**

|                                |        |
|--------------------------------|--------|
| Cobalt + Chromium + Molybdenum | ≥ 85%  |
| Vitallium Alloy                | 98.1%  |
| Vitallium 2 Alloy              | 98.0%  |
| Vitallium Equipoise Alloy      | 98.1 % |
| Vitallium 2000 Alloy           | 98.3%  |
| Vitallium 2000 Plus Alloy      | 98.0%  |
| Cobalt Chrome Casting Alloy    | 97.5%  |

**Mechanical Property Requirements**

| <u>ISO/ANSI/ADA Requirement</u> | 0.2%<br>Yield Strength<br>≥ <u>500 MPa</u> | %<br>Elongation<br>≥ <u>3%</u> |
|---------------------------------|--------------------------------------------|--------------------------------|
| Vitallium Alloy                 | 616                                        | 4.5                            |
| Vitallium 2 Alloy               | 551                                        | 9.6                            |
| Vitallium Equipoise Alloy       | 585                                        | 3.0                            |
| Vitallium 2000 Alloy            | 609                                        | 8.9                            |
| Vitallium 2000 Plus Alloy       | 690                                        | 19.5                           |
| Cobalt Chrome Casting Alloy     | 555                                        | 6.0                            |

Instructions and labels for these products also complies with the ISO and ANSI/ADA standards guidelines.

# AUSTENAL

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## Base Metal Casting Alloys 510(k) Notification Summary

The family of Base Metal Casting Alloys are cobalt chrome casting alloys substantially equivalent to the alloys currently used to produce partial denture frameworks.

Alloys of this type are used extensively in the fabrication of partial dentures and have histories of excellent clinical performance and also complies with ANSI/American Dental Association Specification No. 14 for Base Metal Alloys and ISO 6871 Part 1 for Base Metal Casting Alloys- Cobalt Based.