JUL - 5 2000

K001418

VI. 510(k) SUMMARY

Manufacturer Information:

Sumitomo Chemical Co., Ltd.
Tokyo Sumitomo Twin Bldg. (East)
27-1, Shinkawa 2-chome
Chuo-ku, Tokyo 104-8260
JAPAN

Submitter's Name:

Martin Sterner
Procera Sandvik, Inc.
1872 McBride Avenue
Fair Lawn, NJ 07410
USA

Phone: 201 398-7412
Fax: 201 398-7435

Device Name:

Common Name:	Aluminum Oxide Powder (Sumicorundum AA04S)
Classification Name:	872.6660-Porcelain Powder for Clinical Use
Product Code:	EIH
Class:	II
Panel:	Dental

Indications For Use:

Aluminum Oxide Powder is the raw material used by Procera Sandvik to form a coping to which a porcelain veneer is applied to form a dental crown.

Description:

Aluminum Oxide Powder, is the raw material that, when used in conjunction with computer-assisted design, computer-assisted machining, and sintered to full density, forms a dental coping.

The aluminum oxide powder is compacted against the model of the tooth and is sintered to full density under extreme temperature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2000

Mr. Martin Sterner
Procera Sandvik, Incorporated
1872 McBride Avenue
Fair Lawn, New Jersey 07410

Re: K001418
Trade Name: Aluminum Oxide Powder, Sumicorundum AAO4S
Regulatory Class: II
Product Code: EIH
Dated: May 4, 2000
Received: May 5, 2000

Dear Mr. Sterner:

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

K001418

VIII. INDICATIONS FOR USE

510(k) Number (if known): K001418

Device Name: Aluminum Oxide Powder (Sumicorundum AA04S)

Indications for Use:

Aluminum Oxide Powder is the raw material used by Procera Sandvik to form a coping to which a porcelain veneer is applied to form a dental crown.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001418