JUN 23 1999

K981141

EXHIBIT 6

**510(k) Summary**

Submitted by: Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
1233 20th Street, NW (Suite 700)
Washington, DC 20036
202-261-1000

On behalf of Sargon Enterprises, Inc.
510(k) Submission: Sargon Immediate Load Implant
Alternate collar design
March 27, 1998

The product is an endosseous dental implant for prosthetic attachment; trade name: Sargon Immediate Load Implant™. It is substantially equivalent to previously marketed models of this device described in premarket notifications K930071 and K961005. In this design, the collar is longer and allows the direct fixation of a prosthesis to the implant with or without the use of an abutment.

The material is the same as the predicate devices; *i.e.,* titanium alloy conforming to ASTM standard F136 "Standard Specification for Wrought Titanium 6Al-4V Ell Alloy for surgical Implant Applications." The indications for use are likewise identical: For use in either partially or fully edentulous mandibles and maxillae as a final or intermediary abutment for fixed or detachable prosthesis, and for use in support of free-standing restorations with or without the involvement of adjacent dentition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 1999

Sargon Enterprises, Incorporated
c/o Mr. Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street North West 7th Floor
Washington, DC 20036-3307

Re: K981141
Trade Name: Sargon Immediate Load Implant Model D
Regulatory Class: III
Product Code: DZE
Dated: March, 25 1999
Received: Maarch 29, 1999

Dear Mr. Manelli:

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

**EXHIBIT A**



510(k) Number (if known): **K981141**

Device Name: Sargon Immediate Load Implant - Ultratooth Model

Indications for use:

For immediate load use, without an abutment, in either partially or fully edentulous mandibles and maxillae, for fixed or detachable prosthesis and for use in support of free-standing restorations with or without the involvement of adjacent dentition.

(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)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K981141