

SECTION IV

### Indications for Use

510(k) Number (if known): K080195

Device Name: Nacera Z, Nacera Z Medium

Indications for Use:

Nacera Z and Nacera Z Medium are a dental ceramic designed to be used by dental technicians to manufacture all-ceramic restorations. Nacera Z and Nacera Z medium are Yttria (Yttrium Oxide) stabilized tetragonal zirconia (Zirconia oxide) powder delivered in a partially sintered state.

Nacera Z and Nacera Z Medium is specially designed for use as framework (substructure) for dental restorations, single tooth or bridge type application at anterior and posterior locations.

It is prepared for machining by use of CAM-techniques.

The machined frameworks like dental crown and bridge works are sintered to full density.

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Hein Muehly for MSR

(Division Sign-Off)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

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