

## Indications for Use

510(k) Number (if known)

Device Name

SavDen™ MTA Root Canal Filling Materials

Indications for Use (Describe)

- A root end filling material.
- For the repair of root canals as an apical plug during apexification.
- For repair of root perforations during root canal therapy or as a consequence of internal resorption.
- As a pulp capping material.
- Pulpotomy of primary teeth in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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