DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K181110

Device Name
PROPHYflex 4

Indications for Use *(Describe)*
The PROPHYflex 4 Handpiece and Accessories is a dental handpiece intended for perform supragingival and subgingival prophylaxis treatments. The prophylaxis treatments are obtained by the projection of water, air and appropriate dental prophylaxis powders, onto the treatment site. PROPHYflex 4 Handpiece and Accessories in supra-gingival configuration is intended for use in the cleaning and polishing of teeth by removal soft deposits and areas of discoloration as well as preparing teeth for fillings or veneers and cleaning fixed bands and brackets on orthodontic appliances. PROPHYflex 4 Handpiece and Accessories in subgingival configuration is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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.

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