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)*
K181571

Device Name
OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor

Indications for Use *(Describe)*
The OASYS Oral/Nasal Airway System and OASYS Herbst with Dentitrac ® Patient Monitor is intended to reduce snoring and mild to moderate obstructive sleep apnea (OSA) and monitor patient usage in an adult population.

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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