

Indications for Use

510(k) Number (if known)

K160950

Device Name

MINISCAV™

Indications for Use (Describe)

The MINISCAV™ waste gas evacuation apparatus is intended to remove patients' exhaled waste gases during procedures where analgesia is administered to a patient via inspiration of mixtures of nitrous oxide and oxygen from a nitrous oxide / oxygen delivery device. Not intended for use with flammable anesthetic gases.

This device is intended for professional use only in healthcare facilities, clinics, and physician and dentist offices.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)