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)*

K182287

Device Name

MEDINAUT Plus

Indications for Use *(Describe)*

MEDINAUT Plus Kyphoplasty System is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during balloon kyphoplasty with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

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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