2/10/99

K984117

1. Intended Use:

Innova Corporation requests clearance to market a Telescopic Distractor, an intraoral device which is intended to permit the lengthening of the mandible. The device is designed to allow either unilateral or bilateral distraction. The Innova Telescopic Distractor can allow for up to 18 mm of distraction. The device is intended for use in adult, adolescent or pediatric patients.

2. Device Description:
SUMMARY:

Innova Corporation requests marketing clearance for the Telescopic Distractor, an intraoral subcutaneous device that permits either unilateral or bilateral lengthening of the mandible. The device consists of forward and rear telescoping bodies that are held together by a central element.

The subject device is designed with a central element that can be moved in opposing directions by turning an adjustment screw, producing the telescopic action. The telescoping bodies are attached to the inferior border of the mandibular osteotomy with bone plates and screws. The telescopic elements slide freely in the central element. The maximum amount of distraction possible between the two sections is 18 millimeters.

A circular pin and a separate adjustment screw attaches the forward telescoping element to the forward bone plate. The circular pin provides a rigid, interlocking connection because of the snug fit within the opening in the forward telescoping element. The forward bone plate can be moved transversely relative to the telescopic elements by the adjustment screw. The rear telescopic element is similarly connected to the rear bone plate. The forward and rear bone plate elements are secured to the mandible with four bicortical stainless steel bone screws.

Following placement of the distractor, the clinician waits for a period of 5 to 10 days to allow for intraoral healing prior to initiating distraction.

The Innova Telescoping Distractor is made from wrought surgical grade stainless steel. The material conforms to ASTM F 138-97. This material is currently used in a variety of implanted devices such as bone plates and has a demonstrated biocompatibility by its long history of use for implant applications.

The Telescoping Distractor is available in two models; unilateral and bilateral. The devices are operated and applied in an identical manner, except that the unilateral model is intended for distraction osteogenesis of either the right or the left side of the mandible, while the bilateral model is intended to be used for simultaneous distraction osteogenesis of both the right and left sides of the mandible.

The device is indicated for the following procedures:

- mandibular body lengthening
- mandibular ramus lengthening
- distraction osteogenesis across a mandibular segmental defect in the ramus, body or symphysis
- transport distraction osteogenesis across a mandibular segmental defect in the ramus, body, or symphysis

The device is indicated for use in adult, adolescent and pediatric patients.

The sponsor claims substantial equivalence to the previously cleared devices intended for use in distraction osteogenesis, such as the Howmedica, Inc. Mandibular Distractor II, cleared

as K960297. The devices share the same intended use and principle of operation. The devices share similar technological characteristics.

The Howmedica Mandibular Bone Distractor II (K960297) was cleared for use in adults and children. The predicate device is intended as both a stabilizer and bone lengthener through distraction of the mandible. The predicate device is supplied non-sterile and is labeled for single use only. The Innova device is also supplied non sterile. Sterilization instructions are included in the draft labeling included as attachment 8 in the document. The labeling clearly states that the device is intended for single use only and should therefore not be resterilized for reuse by any method. The product is packaged in Tyvek and is ready for processing in the autoclave.

ANALYSIS:

The subject device, the Innova Telescopic Distractor is substantially Equivalent to previously cleared devices for a similar intended use.

RECOMMENDATIONS:

SUBSTANTIALLY EQUIVALENT

Sandra L. Shire, DMD.

Sandra L. Shire, DMD, MPA
Dental Officer, DeDB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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FEB 10 1999

Innova Corporation
C/O Howard M. Holstein, Esq.
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K984117
Trade Name: Innova Telescopic Distractor
Regulatory Class: II
Product Code: MQN
Dated: November 16, 1998
Received: November 17, 1998

Dear Mr. Holstein

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Innova Telescopic Distractor

Indications For Use:

The Telescopic Distractor is an intraoral, subcutaneous distractor which is used for mandibular distraction osteogenesis. The device is indicated for use in patients with congenital micrognathia, post-traumatic mandibular deformities, or defects resulting from tumor resection. In conjunction with osteotomy or corticotomy, the Telescopic Distractor may be used for:

- mandibular body lengthening;
- mandibular ramus lengthening;
- distraction osteogenesis across a mandibular segmental defect in the ramus, body, or symphysis; and
- transport distraction osteogenesis across a mandibular segmental defect in the ramus, body, or symphysis.

The device may be used in adult, adolescent, or pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984117

(Optional Format 1-2-96)