

MAY 20 1998



AUTOGENESIS

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Section I: Premarket 510(k) Device Modification Summary

As required by section 807.92(c).

Applicant and Company's Name: Autogenesis™ Inc.
Address: Autogenesis Inc.
 410 West Lombard St. Suite 217
 Baltimore, MD 21201

Contact Person: James Edwards, President of Autogenesis Inc.

Date Summary was Prepared: April 10, 1998

Trade or Proprietary Name: Autogenesis™ Automator 2000

Common or Usual Name: Automatic distraction component for external fixation devices.

Classification Name: Orthopedic Device: (Component for) smooth or threaded metallic bone fixation fastener.

Predicate Device to which Equivalence is Claimed:

The Autogenesis™ Automator 2000 is a modified version of the CF Automator, also manufactured by Autogenesis™ Inc. Automator 2000 is substantially equivalent in terms of safety and effectiveness to the CF Automator. The predicate device received clearance in 1991 under 510(k) Premarket Notification Number K905514.

Device Description:

Distraction osteogenesis is the process by which our bodies are able to "grow" bone and soft tissues at a fracture site if the bone fragments are gradually separated at a rate approximating 1 mm per day. Automator 2000 is a simple battery powered, motorized device used to accomplish precision distraction for the purpose of bone and soft tissue (re)generation. The programmable device is used as a component on commonly available external fixation frames. Specifically, the device accomplishes micro-adjustments of a telescoping rod, which, in turn, positions the external frames, and bone segments to which the frames are attached.

Adjustment of external frames for bone positioning is presently performed by the CF Automator or manual adjustment techniques. Automator 2000 is a modified version of the CF Automator. It has been simplified to eliminate the necessity for a separate programming computer, external controller, external cables, and custom battery pack. It has been improved by raising mechanical performance and reducing power requirements.

Modifications to the predicate device include the devices housing, motor, gearing, circuitry, software, and power supply. The mechanical design of Automator 2000 is similar to the design of the CF Automator drive units. The modified device also uses the CF Automator's safety and self diagnostic features. For further description of Automator 2000 please see the body of this 510(k) application.

Indications for use:

The Autogenesis™ Automator™2000, in conjunction with standard, commercially available circular and unilateral fixation devices, may be used to perform controlled adjustment and positioning of long bones. Automator 2000 may replace the CF Automator™ or manual adjustment devices where they are traditionally applied. Indications for such use include the following:

- ◆ the correction of bony or soft tissue deformities,
- ◆ limb lengthening by epiphyseal and metaphyseal distraction,
- ◆ bone thickening and/or lengthening of amputated stumps,
- ◆ fracture fixation (open or closed),
- ◆ pseudoarthrosis or non-union of long bones,
- ◆ correction of segmental bony or soft tissue defects.

Summary of How Technical Characteristics of Automator 2000 Compare to the CF Automator:

Power: Automator 2000 requires substantially less power than the CF Automator. Automator 2000 is powered by a 9 volt battery rather than a custom lithium battery pack of 10 cells (21 volts for the drive units plus 14 volts for the controller). Automator 2000 is expected to run 3.5 months on a lithium 9 volt battery, and 3.5 weeks on an alkaline 9 volt battery. The CF Automator runs approximately 3 weeks on its custom pack.

Precision: Automator 2000 makes use of a robust DC motor and braking system that is able to maintain impressive accuracy. As a result of the motor choice, the software algorithm for controlling the motor adjustments may demand a high level of precision for the telescoping rod adjustment. Automator 2000 maintains accuracy within 1/72 mm. This compares to CF Automator accuracy of 1/32mm.

Motor Control: Automator 2000 uses a DC Motor with a gear reduction ratio of 5752:1, resulting in a high torque and slow RPM output. This compares to the stepper motor used in the CF Automator, which uses 0.36 degree step angles. Both motors provide precise micro-motion that can be controlled by the respective device's CPU.

The motor chosen for Automator 2000 provides higher torque, is a preferable size for the Automator 2000 housing design, and requires less power.

Housing & Enclosure: The CF Automator (predicate device) has separately enclosed components that mount to the external fixator frame: drive units, controller, and battery pack. The components are connected by cables. By comparison, Automator 2000 has the control circuitry, drive components, and battery contained in a single housing. The compact and entirely self contained design of Automator 2000 simplifies the installation of the product. Furthermore, external cables are no longer vulnerable to damage or being inadvertently unplugged in the design of Automator 2000.

Automator 2000's machined aluminum housing is a robust design that comfortably accommodates the axial force and impact load requirements of the device. Additionally, the conductive aluminum housing has been designed to preclude radio frequency interference. By comparison, the CF Automator components are housed in delrin (a plastic composite), which is shaped by plastic injection molding.

Circuitry and Software/ Safety Features: Automator 2000's design has retained the CF Automator's redundant self diagnostic and circuitry controls to assure that the telescoping rod may move only the *amount* it is intended to move, and only *when* it is intended to move. Since each Automator 2000 device has its own control circuitry, the complexity built into the CF Automator circuitry for controlling multiple drive units has been removed. Since Automator 2000 is programmed using switches on the control board rather than through an IR communication link to a doctor's master computer, further communication circuitry has also been rendered unnecessary. Consequently, Automator 2000 has a more simplified circuit board and software package.

Programming the device has been simplified as well. The predicated device (CF Automator) allowed the physician to choose from 14 rate settings and 7 rhythm settings for the number of adjustment increments made by the device each day. Automator 2000 has 7 rate setting to chose from and the movement amount per increment is held constant at 1/360th mm.

Regarding motor control, Automator 2000 and the CF Automator very similar software and circuitry safety features. Certain conditions that applied to the CF Model do not apply to Automator 2000 – for example, an unplugged drive unit or unplugged battery. Similarities between the two operating systems include the following: Both systems have been designed to use the *final* drive gear as an encoder to verify the position of the telescoping rod. Each system will error if the encoder does not verify that distraction is progressing within tolerable accuracy. Both systems check current on the motor circuit to verify the motor runs only when it is supposed to, and furthermore, check current during motor pulses to verify that current is not higher than expected. Both motor circuits have switches that remain open between motor pulses to prevent the motor from receiving current. Both systems use a watch-dog circuit to confirm software operation nearly continuously. Both systems have redundant audio and visual alarms. Furthermore, both units use the same design telescoping rod, which may be used to make manual lengthening adjustments at any time.

Performance Characteristics for Load on Telescoping Rod: Automator 2000 was designed to handle more axial load than the CF Automator drive units. In procedures where CF Automator drive units have been placed on non-parallel rings CF Model drive units have occasionally experienced sufficient side-loading to create excessive resistance on the motor. While this may be remedied by using conical washers on the rings to better align drive units, Automator 2000 has been designed to accommodate additional resistance that can be experienced as the result of such side-loading.

Automator 2000 is designed to alarm when resistance approximates an axial load of 250 lbs. (175 lbs. axial load and the equivalent of 75 lbs. axial load resistance from side loading). The CF Automator was designed to accommodate an axial load of 125 lbs. Additionally, Automator 2000 has been designed and tested to accommodate impact loads of 50 lbs. on the telescoping rod.

In summary, modifications made to the design of the CF Automator have succeeded in simplifying and improving the device in several areas. Automator 2000 continues to use the same safety controls that are responsible for the CF Automator's record of safe and effective use.

Non-Clinical Performance Testing:

Automator 2000 was designed in accordance to the design control guidance for medical device manufacturers published March 17, 1997. As a part of the verification exercises performed during the product modification and design process, multiple tests were conducted. Testing was performed to verify the following: 1. The motor selected would generate sufficient torque. 2. The motor would not require excessive power. 3. The motor output speed would be slow enough to control with the processor, but fast enough to be energy efficient. 4. A 9 volt battery would be adequate to power the device, 5. The software algorithm used to control the motor would reliably assure accuracy to 1/72 mm. 6. All mechanical components selected would be adequate to sustain specified levels of axial and impact loading. 7. Integration, and verification of all functions, error modes, and self diagnostic procedures in the product's software and hardware had been accomplished 8. Electrostatic discharge, Electromagnetic Compatibility Studies would confirm compliance with standard IEC 60601-1-2.

Furthermore a traceability matrix was maintained to assure that all design input has been accomplished by the design of the device. All testing confirmed that the design for Automator 2000 was safe and effective, and that the predetermined design input had been properly implemented.

Further design validation was performed through dynamic testing of the device under variable loads, temperatures, and battery voltages. Life testing of the device further confirmed the battery life expectancy and documented continuous error free operation.

Design controls for the device modifications were implemented at the initiation of the project. Hence, the design was subject to thorough review during the entire modification/design process. Autogenesis retains clear documentation of input requirements, design output, design reviews, verification activities, and validation activities

In summary, the Automator 2000 model was designed to be as safe and effective as Autogenesis' CF model. Design verification and validation activities have demonstrated that the design requirements have been fully and properly implemented. In light of the design controls maintained by Autogenesis, and in light of the studies and testing performed on Automator 2000 that confirm its safety and effectiveness, Automator 2000 has been demonstrated to be substantially equivalent in safety and effectiveness to the CF Automator.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Mr. James Edwards
President
Autogenesis, Inc.
410 West Lombard Street, Suite 217
Baltimore, Maryland 21201

Re: K981423
Trade Name: Autogenesis™ Automator 2000
Regulatory Class: II
Product Codes: JEC and HTY
Dated: February 18, 1998
Received: April 20, 1998

Dear Mr. Edwards:

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.

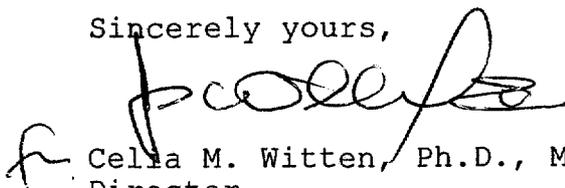
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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.

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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) 594-4659. 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,



h. Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K981423

Section IV. Intended Use of the Device

The Autogenesis™ Automator™2000, in conjunction with standard, commercially available circular and unilateral fixation devices, may be used to perform compression or distraction on long bones. The Automator™2000 may replace the CF Automator™ or manual distraction and compression devices where they are traditionally applied. Indications for such use include the following:

- ◆ the correction of bony or soft tissue deformities,
- ◆ limb lengthening by epiphyseal and metaphyseal distraction,
- ◆ bone thickening and/or lengthening of amputated stumps,
- ◆ fracture fixation (open or closed),
- ◆ pseudoarthrosis or non-union of long bones,
- ◆ correction of segmental bony or soft tissue defects.

Prescription Use X
(Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)
Division of Medical Restorative Devices
510(k) Number K981423