

DEC - 8 1999

## 510(k) Summary

510(k) Number K991882

### *Manufacturer Identification*

**Submitted By:** Nexmed, Inc.  
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**Contact Person:** Jason Blain  
Manager of Product Development

**Date Summary Prepared:** May 21, 1999

### *Device Identification*

**Proprietary Name:** NexFlex Total Knee System

**Common Name:** Semi-constrained total knee prosthesis

**Classification:** 21 CFR 888.3560: Prosthesis, Knee, Patellofemorotibial,  
Semi-constrained, Cemented, Polymer/Metal/Polymer

### *Device Description*

The NexFlex Total Knee System consists of femoral components, tibial base components, tibial inserts, all-polyethylene tibial components, cancellous bone screws, a tibial screw hole cap, tibial stem extensions, and patellar components. The components of this system are designed to be used together and cannot be used as part of another system, nor can components of another system be incorporated into use with the NexFlex Total Knee System.

NexFlex femoral components are manufactured from cobalt-chromium alloy and are available in a range of sizes and in left and right orientations. They are available with or without a commercially pure titanium plasma sprayed inner surface.

Tibial base components are manufactured from titanium (Ti-6Al-4V) alloy and are available in a range of sizes. They are available with or without a commercially pure titanium plasma sprayed distal surface.

Tibial inserts are manufactured from ultra-high molecular weight polyethylene and are available in a range of sizes to match the tibial base components. The distal side of the tibial inserts has geometry to allow a mechanical lock to the tibial base components of

corresponding size. The proximal side of the tibial inserts has geometry that allows articulation with the femoral components. Tibial inserts are available with two different proximal geometries, allowing for different amounts of constraint and contact area with the femoral components. A number of thicknesses of inserts are offered.

All-polyethylene tibial components are manufactured from ultra-high molecular weight polyethylene and are available in a range of sizes and thicknesses. These components have distal geometry similar to the tibial base components and proximal geometry similar to the tibial inserts.

Cancellous bone screws are manufactured from titanium (Ti-6Al-4V) alloy and are available in a range of lengths. The screws are designed to go through the tibial base component to secure it to the proximal tibia.

Tibial screw hole caps are manufactured from titanium (Ti-6Al-4V) alloy. They are designed to thread into the tibial base components to cover the screw holes when a cancellous bone screw is not used.

Tibial stem extensions are manufactured from titanium (Ti-6Al-4V) alloy and are available in a range of diameters and lengths. The stems are designed to mate with the tibial base components by means of a mechanical engagement.

Patellar components are manufactured from either ultra-high molecular weight polyethylene or a combination of ultra-high molecular weight polyethylene and titanium (Ti-6Al-4V) alloy. They are designed with posterior geometry that allows articulation with the femoral components. Patellar components with titanium backing have a commercially pure titanium plasma sprayed anterior surface.

### ***Intended Use of the Device***

The NexFlex Total Knee System is indicated for:

- Painful, disabling joint disease resulting from rheumatoid arthritis, post-traumatic arthritis, osteoarthritis, or degenerative arthritis
- Failed osteotomies, unicompartmental replacement, or total knee replacement
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability

The NexFlex Total Knee System is intended for cemented use only.

### ***Substantial Equivalence***

The NexFlex Total Knee System is substantially equivalent to the following knee systems: Miller/Gallante Total Knee System (Zimmer, Inc.), AGC Total Knee System (Biomet, Inc.), AMK Total Knee System (DePuy, a Johnson & Johnson Company), Series 7000 Total Knee System (Stryker/Osteonics). The NexFlex Total Knee System is



similar to each of the listed predicate devices in one or more of the following areas: design, function, materials used, and indications for use.

***Non-Clinical Performance Data***

Mechanical testing of the NexFlex Total Knee System was performed in accordance with the recommended testing listed in the Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses. Testing indicated that the system is capable of withstanding *in vivo* loading without failure.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jason Blain  
Manager of Product Development  
Nexmed Incorporated  
42-160 State Street  
Palm Dessert, California 92211

Re: K991882  
Trade Name: NexFlex Total Knee System  
Regulatory Class: II  
Product Codes: JHW  
Dated: May 28, 1999  
Received: June 2, 1999

Dear Mr. Blain:

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,

*for* 

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Indications for Use**

510(k) Number: K991882

Device Name: NexFlex Total Knee System

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(Division Sign-Off)

Division of General Restorative Devices

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Prescription Use X  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_