### 510(k) Summary of Safety and Effectiveness

**Stryker Spine Trio® Plate System**

| Submitter: | Stryker Spine  
| 2 Pearl Court  
| Allendale, New Jersey 07401 |
|---|---|
| Contact Person | Ms. Simona Voic  
Regulatory Affairs Project Manager  
Phone: 201-760-8145  
FAX: 201-760-8345  
Email: simona.voic@stryker.com |
| Date Prepared | April 17, 2007 |
| Trade Name | Stryker Spine Trio® Plate System |
| Proposed Class | Class III |
| Classification Name and Number | Pedicle Screw Spinal System  
[21 CFR 888.3070(b) (1) & (b) (2)] |
| Product Code | NKB, MNH, and MNI |
| Predicate Devices | K043180 – Stryker Spine Trio® Plate System (PS)  
K060361 – Stryker Spine Xia® and Xia® 4.5 Spinal Systems  
K060369 – Stryker Spine Opus™ Spinal System |
| Device Description | The Stryker Spine Trio® Plate System is comprised of spinal screws, plates and locking components, fabricated from Titanium alloy. |
| Intended Use | The Stryker Spine Trio \(^*\) Plate System is intended for posterior, noncervical (T10-S1) pedical and nonpedical fixation of the spine for the following indications:  
- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);  
- Spondylolisthesis;  
- Trauma (i.e., fracture or dislocation);  
- Spinal stenosis;  
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);  
- Tumor;  
- Pseudoarthrosis; and  
- Failed previous fusion. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of the Technological Characteristics</td>
<td>Testing in compliance with FDA’s Guidance for Spinal System 510(k)’s May 3, 2004 was performed for the Stryker Spine Trio (^*) Plate System and was presented in their respective predicate 510(k)s. This 510(k) contains no new components. It only addresses the additional Class III indications associated with product code NKB.</td>
</tr>
</tbody>
</table>
### 510(k) Summary of Safety and Effectiveness

#### Stryker Spine Trio® Spinal Fixation System

<table>
<thead>
<tr>
<th>Submitter:</th>
<th>Stryker Spine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 Pearl Court</td>
</tr>
<tr>
<td></td>
<td>Allendale, New Jersey 07401</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Person</th>
<th>Ms. Simona Voic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regulatory Affairs Project Manager</td>
</tr>
<tr>
<td></td>
<td>Phone: 201-760-8145</td>
</tr>
<tr>
<td></td>
<td>FAX: 201-760-8345</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:simona.voic@stryker.com">simona.voic@stryker.com</a></td>
</tr>
</tbody>
</table>

| Date Prepared    | April 17, 2007      |

| Trade Name       | Trio® Spinal Fixation System |

| Proposed Class   | Class III             |

| Classification Name and Number | Pedicle Screw Spinal System 21 CFR 888.3070(b) (1) & (b) (2) |

| Product Code     | NKB, MNH, and MNI    |

| Predicate Devices | K032855 – Stryker Spine MAPS System |
|                  | K052971 - Stryker Spine Trio® Spinal Fixation System |
|                  | K060361 – Stryker Spine Xia® and Xia® 4.5 Spinal Systems |

| Device Description | The Stryker Spine Trio® Spinal Fixation System is comprised of spinal screws, rods, and offset connectors, fabricated from Titanium alloy. |
| Intended Use | The Stryker Spine Trio® Spinal Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine. The Stryker Spine Trio® Spinal Fixation System is indicated for:  
- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);  
- Spondylolisthesis;  
- Trauma (i.e., fracture or dislocation);  
- Spinal stenosis;  
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);  
- Tumor;  
- Pseudoarthrosis; and  
- Failed previous fusion.  
The Trio® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors. |
| Summary of the Technological Characteristics | Testing in compliance with FDA’s Guidance for Spinal System 510(k)’s May 3, 2004 was performed for the Stryker Spine Trio® Spinal Fixation System and presented in K032855 and K052971. This 510(k) contains no new components. It only addresses the additional Class III indications associated with product code NKB. |
### 510(k) Summary of Safety and Effectiveness

**Stryker Spine Trio®+ Spinal System**

| Submitter: | Stryker Spine  
| 2 Pearl Court  
| Allendale, New Jersey 07401 |
| Contact Person | Ms. Simona Voic  
| Regulatory Affairs Project Manager  
| Phone: 201-760-8145  
| FAX: 201-760-8345  
| Email: simona.voic@stryker.com |
| Date Prepared | April 17, 2007 |
| Trade Name | Stryker Spine Trio®+ Spinal System |
| Proposed Class | Class III |
| Classification Name and Number | Pedicle Screw Spinal System  
| 21 CFR 888.3070(b) (1) & (b) (2) |
| Product Code | NKB, MNH, and MNI |
| Predicate Devices | K052971 - Stryker Spine Trio® Spinal Fixation System  
| K062698 - Stryker Spine Trio®+ Spinal System  
| K060361 - Stryker Spine Xia® and Xia® 4.5 Spinal Systems |
| Device Description | The Stryker Spine Trio®+ Spinal System contains spinal screws, rods, and connectors, fabricated from Titanium alloy. This submission adds the Class III indications per product code NKB, |
Stryker Spine Trio® PS, Trio® Spinal Fixation System & Trio®+ Spinal System

21 CFR 888.3070(b)(2), but no additional components. The expanded indications for use statement for the TRIO®+ Spinal System has also been modeled on the suggested indications for use statement for posterior thoracolumbar systems (product codes MNI, MNH, NKB) suggested by FDA in FDA’s “Guidance for Industry and FDA Staff: Spinal System 510(k)s,” dated May 3, 2004.

**Intended Use**

The Stryker Spine Trio®+ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine.

The Stryker Spine Trio®+ Spinal System is indicated for:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Trio®+ Spinal System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, Xia® Pre-bent Rods, and the Multi-Axis Cross Connectors.
| Summary of the Technological Characteristics | Testing in compliance with FDA’s Guidance for Spinal System 510(k)’s May 3, 2004 was performed for the Stryker Spine Trio® Spinal System, and was presented in the respective predicate 510(k)s. This 510(k) contains no new components. It only addresses the additional Class III indications associated with product code NKB. |

Stryker Spine Trio® PS, Trio® Spinal Fixation System & Trio®+ Spinal System

Traditional 510(k) Premarket Notification
Stryker Spine Corporation
c/o Ms. Simona Voic
2 Pearl Court
Allendale, New Jersey 07401

Re: K070368
Trade Name: TRIO® Plate System, TRIO® Spinal Fixation System, TRIO®+ Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNH,MNI
Dated: April 13, 2007
Received: April 17, 2007

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the device are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K070368

Device Name: Stryker Spine Trio® Plate System

Indications For Use:

The Stryker Spine Trio® Plate System is intended for posterior, noncervical (T10-S1) pedicle and nonpedicle fixation of the spine for the following indications:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

Prescription Use ___X___ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070368
Indications for Use

510(k) Number (if known): K070368
Device Name: Stryker Spine Trio® Spinal Fixation System

Indications For Use:

The Stryker Spine Trio® Spinal Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine.

The Stryker Spine Trio® Spinal Fixation System is indicated for:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Trio® Spinal Fixation System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, and the Multi-Axis Cross Connectors.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070368
Indications for Use

510(k) Number (if known): K070368
Device Name: Stryker Spine Trio®+ Spinal System

Indications for Use:

The Stryker Spine Trio®+ Spinal System is intended for posterior, noncervical pedicle and non-pedicle fixation of the spine.

The Stryker Spine Trio®+ Spinal System is indicated for:
- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Trio®+ Spinal System is intended to be used in conjunction with the OSS Diapason Rods, Opus Spinal System Rods, Xia® Pre-bent Rods, and the Multi-Axis Cross Connectors.

Prescription Use ___X___ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
Division of General, Restorative, and Neurological Devices

510(k) Number K070368