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SECTION 2. SUMMARY AND CERTIFICATION

2.A. 510(k) Summary

Submitter:	SterilMed, Inc.
Contact Person:	Thomas A. Dold MBA, RAC Director of Regulatory Affairs SterilMed, Inc. 11400 73rd Ave. N Minneapolis, MN 55369 Ph: 763-488-3400 Fax: 763-488-3350
Date Prepared:	July 18, 2005
Trade Name:	Reprocessed External Fixation Device
Classification Name: **And Number:**	External Fixation Device Class II, 21 CFR 888.3030
Product Code:	KTT
Predicate Device(s):	The Reprocessed External Fixation Device is substantially equivalent to the Synthes Reprocessed External Fixation Devices (K033158), Synthes Large External Fixation Clamps MR Safe (K031428) and Synthes Medium External Fixation System MR Safe (K040258).
Device Description:	The Reprocessed External Fixation Device consists of the standard bridge elements (rods, articulating and telescoping components), and connection elements (clamps) contained in the original manufacturer's system. Some of the components are MR safe and made of non-magnetic materials. MR safe components are intended for use in the MR environment. Anchorage elements are not included in the Reprocessed External Fixation Device.
Intended Use:	The Reprocessed External Fixation Device is intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.

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Functional and Safety Testing:

Representative samples of Reprocessed External Fixation Devices underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning procedure. In addition, the manufacturing process includes visual and functional testing of all products prior to release.

Conclusion:

The External Fixation Device reprocessed by SterilMed is substantially equivalent to counterpart devices originally manufactured by Synthes. This conclusion is based upon the devices' similarities in functional design, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Mr. Thomas A. Dold, MBA, RAC
Director of Regulatory Affairs
SterilMed, Inc.
11400 73rd Avenue North
Minneapolis, Minnesota 55369

Re: K051957
Trade/Device Name: Reprocessed External Fixation Device
(See enclosed list)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: July 18, 2005
Received: July 19, 2005

Dear Mr. Dold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is 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 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 (PMA), 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 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 device complies 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 device as described in your Section 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), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

Enclosure

Reprocessed External Fixation Device Models found to be **Substantially Equivalent**:

Large External Fixation Device Components

	Manufacturer #	Description
1.	390.002	Large 6 Position Multi-Pin Clamp, MR Safe
2.	390.003	Rod Attachment for Large Multi-Pin Clamp, MR Safe
3.	390.004	Large 4 Position Multi-Pin Clamp, MR Safe
4.	390.005	Large Combination Clamp, MR Safe
5.	390.006	Dynamization Clip for Large Combination Clamp, MR Safe
6.	390.007	Tube-to-Tube Clamp, MR Safe
7.	390.008	Large Open Adjustable Clamp, MR Safe
8.	394.80	11.0mm Carbon Fiber Rod, 100mm length
9.	394.81	11.0mm Carbon Fiber Rod, 125mm length
10.	394.82	11.0mm Carbon Fiber Rod, 150mm length
11.	394.83	11.0mm Carbon Fiber Rod, 200mm length
12.	394.84	11.0mm Carbon Fiber Rod, 250mm length
13.	394.85	11.0mm Carbon Fiber Rod, 300mm length
14.	394.86	11.0mm Carbon Fiber Rod, 350mm length
15.	394.87	11.0mm Carbon Fiber Rod, 400mm length

Medium External Fixation Device Components

	Manufacturer #	Description
16.	390.031	Medium Combination Clamp, MR Safe
17.	390.032	Dynamization Clip for Medium Combination Clamp, MR Safe
18.	390.033	Medium 4 Position Multi-Pin Clamp, MR Safe
19.	390.034	Rod Attachment for Medium Multi-Pin Clamp, MR Safe
20.	390.035	Medium Open Adjustable Clamp, MR Safe
21.	390.036	Medium 6 Position Multi-Pin Clamp, MR Safe
22.	390.037	8.0mm/11.0mm Combination Clamp, MR Safe
23.	395.779	8.0mm Carbon Fiber Rod, 160mm length
24.	395.780	8.0mm Carbon Fiber Rod, 180mm length
25.	395.782	8.0mm Carbon Fiber Rod, 200mm length
26.	395.784	8.0mm Carbon Fiber Rod, 220mm length
27.	395.786	8.0mm Carbon Fiber Rod, 240mm length
28.	395.788	8.0mm Carbon Fiber Rod, 280mm length
29.	395.792	8.0mm Carbon Fiber Rod, 320mm length
30.	394.796	8.0mm Carbon Fiber Rod, 360mm length
31.	394.797	8.0mm Carbon Fiber Rod, 400mm length

Small External Fixation Device Components

	Manufacturer #	Description
32.	390.041	Small Combination Clamp, MR Safe
33.	390.051	4.0mm Adjustable Clamp for Distal Radius Fixator, MR Safe
34.	395.54	4.0mm/2.5mm Open Clamp
35.	395.55	4.0mm/4.0mm Open Clamp
36.	395.56	4.0mm/2.5mm Clamp
37.	395.57	4.0mm/4.0mm Clamp
38.	395.597	4.0mm Adjustable Clamp for Distal Radius Fixator
39.	395.60	4.0mm Carbon Fiber Rod, 60mm length
40.	395.61	4.0mm Carbon Fiber Rod, 80mm length
41.	395.62	4.0mm Carbon Fiber Rod, 100mm length
42.	395.63	4.0mm Carbon Fiber Rod, 120mm length
43.	395.64	4.0mm Carbon Fiber Rod, 140mm length
44.	395.65	4.0mm Carbon Fiber Rod, 160mm length
45.	395.66	4.0mm Carbon Fiber Rod, 180mm length
46.	395.67	4.0mm Carbon Fiber Rod, 200mm length

Mini External Fixation Device Components

	Manufacturer #	Description
47.	395.105	3.0mm Carbon Fiber Rod, 25mm length
48.	395.107	3.0mm Carbon Fiber Rod, 45mm length
49.	395.109	3.0mm Carbon Fiber Rod, 60mm length
50.	395.111	3.0mm Carbon Fiber Rod, 75mm length
51.	395.125	Mini Holding Clamp, 1.25mm
52.	395.126	Mini Holding Clamp, 1.6mm
53.	395.133	3.0mm/3.0mm Connecting Clamp
54.	395.134	3.0mm/4.0mm Connecting Clamp

Indications for Use

510(k) Number (if known): K051957 (pg 1 of 2)

Device Name: Reprocessed External Fixation Device

Indications for Use:

The Reprocessed External Fixation Device is intended for use in the construction of an external fixation frame for treatment of various fracture types that require external fixation.

LARGE
Provide treatment for long bone and pelvic fractures that require external fixation Specifically, the components are used for:

- Stabilization of soft tissues and fractures
- Polytrauma/multiple orthopedic trauma
- Vertically stable pelvic fractures, or as treatment adjunct for vertically unstable pelvic fractures
- Arthrodeses and osteotomies with soft tissue problems; failures of total joints
- Neutralization of fractures stabilized with limited internal fixation
- Non-unions/septic non-unions
- Intra-operative reductions/stabilization tool to assist with indirect reduction
- Unilateral rectilinear bone segment transport or leg lengthening

MEDIUM
Indicated for construction of an external fixation frame for the treatment of pediatric and adult fractures.

SMALL
Stabilizes and provides treatment for fractures of the small bones, such as the hand, wrist, forearm, foot and ankle Specifically, the components can be used for:

- Preliminary fixation before ORIF
- Unstable fractures of the distal radius (both intra and extra-articular)
- Open and/or comminuted bilateral fractures
- Fractures in combination with extensive soft tissue injury, bone loss, and vascular and/or neural involvement
- Fracture dislocations
- Failed closed reduction with casting resulting in secondary deformity (radial shortening and angulations)
- Pediatric open fractures with bone loss and osteotomies

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MINI
Stabilizes and provides treatment for fractures of the hand and foot Specifically, the components can be used for:

- Comminuted fractures of phalanges and metacarpals
- Displaced intra-articular fractures
- Segmental bone loss
- Open fractures that do not allow stable internal fixation
- Fractures with associated complex soft tissue injuries
- Tumor resections

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)

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