

Exhibit I
510(k) Summary
Sundt Slim-Line Aneurysm Clip Applier

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

1. Contact Person:

Janet G. Johnson
Associate Regulatory Affairs Specialist
(508) 828-3466

2. Device Information:

<i>Proprietary Name:</i>	Sundt Slim-Line Aneurysm Clip Applier
<i>Common Name:</i>	Aneurysm Clip Applier
<i>Classification Name:</i>	Aneurysm Clip Applier
<i>Regulatory Class:</i>	Class II, per 21 §CFR 882.4175
<i>Product Code:</i>	84 HCI

3. Indications for Use:

The Sundt Slim-Line Aneurysm Clip Applier is designed for use only with Sundt Slim-Line Aneurysm Clips.

4. Device Description:

The subject Sundt Slim-Line Aneurysm Clip Applier is a stainless steel reusable hand-held instrument that is available in two configurations a fixed tip applier and a hinged tip applier. All three appliers consist of a handle grip with serrations, a two-piece spring, a shaft, and a v-grooved shape tip for grasping the aneurysm clip. The fixed tip Sundt Slim-Line Aneurysm Clip Applier and the Sugita appliers are designed with shaft that angles down and a thin tip profile to provide the surgeon a greater field of view during clip placement.

5. Substantial Equivalence:

The determination of substantial equivalence for the Sundt Slim-Line Aneurysm Clip Applier was based on a detailed device description, intended use, materials, design, sterilization, and packaging to the Aneurysm Clip Applier (K791764A) and the Sugita Aneurysm Clip Applier (K791978).



DEC 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Janet G. Johnson, RAC
Associate Regulatory Affairs Specialist
Johnson and Johnson Professional, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K982379
Trade Name: Sundt Slim-Line Aneurysm Clip Applier
Regulatory Class: II
Product Code: HCI
Dated: October 29, 1998
Received: October 30, 1998

Dear Ms. Johnson:

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.

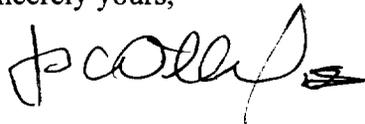
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Ms. Janet G. Johnson

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) 594-4595. 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,



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

Enclosure

K982379

510(k) Number (if known)

Device Name

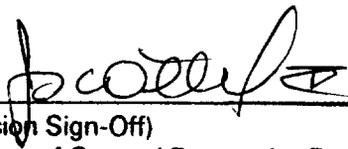
Sundt Slim-Line Aneurysm Clip Applier

Indications For Use

The Sundt Slim-Line Aneurysm Clip Applier is designed for use only with Sundt Slim-Line Aneurysm Clips.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K982379

Prescription Use
 (Per 21 CFR §801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)