

510(k) SUMMARY

DEC 14 2007

510(k) Owner: Anika Therapeutics, S.r.l. (former Fidia Advanced Biopolymers, S.r.l.)
Via Ponte dell Fabbrica 3/B
35031 Abano Terme
PADOVA, ITALY

Contact: Dr. Adriano Zanotti
Regulatory Affairs
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Date Summary Prepared: May 19, 2011 (*Revised*)

Device: Trade Name: HYALOMATRIX®
Common/Classification Name: Wound Dressing
Product Code FRO
Classification: Unclassified

Predicate Devices: HYALOMATRIX™ KC (Laserskin) Wound Dressing
Fidia Advanced Biopolymers S.r.l.
K001508

Bilayer Matrix Wound Dressing
Integra LifeSciences Corporation
K021792

Oasis Wound Matrix
Cook Biotech, Inc.
K061711

Device Description: HYALOMATRIX is a bilayered, sterile, flexible, and conformable wound dressing that acts as an advanced wound care device. It is comprised of a non-woven pad entirely composed of HYAFF 11, a benzyl ester of hyaluronic acid, and a semipermeable silicone membrane, which controls water vapor loss, provides a flexible covering for the wound surface, and adds increased tear strength to the device. The HYAFF 11 wound contact layer biodegradable matrix acts as a scaffold for cellular invasion and capillary growth.

Intended Use: HYALOMATRIX is indicated for the management of wounds including: partial and full-thickness wounds; second-degree burns; pressure ulcers; venous ulcers; diabetic ulcers; chronic vascular ulcers; tunneled/undetermined wounds; surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence); trauma wounds (abrasions, lacerations, skin tears); and draining wounds. The device is intended for one-time use.

Technological Characteristics: Similar to the predicate devices, HYALOMATRIX is a biologically-derived wound dressing that provides a scaffold for in-growing cells, and like the Integra Bilayer Matrix Wound Dressing, it contains a semipermeable silicone

	layer to prevent moisture loss.
Biocompatibility Data:	<p>The biocompatibility of HYAFF 11 (powder or film), one component of HYALOMATRIX, was assessed in a series of <i>in vitro</i> and <i>in vivo</i> studies.</p> <p>Cytotoxicity and hemolysis studies demonstrate that HYAFF 11 films are neither cytogenic nor hemolytic. Acute oral and dermal toxicity studies on HYAFF 11 powder indicate that the lethal dose of HYAFF 11 is greater than 5,000 mg/kg and 2,000 mg/kg, respectively. Irritation studies demonstrate that HYAFF 11 powder is not an ocular or dermal irritant, and a sensitization study provides evidence for the lack of a sensitizing effect. No evidence of genotoxicity was observed in three <i>in vitro</i> assays or one <i>in vivo</i> study. An implantation study of up to 1 year found no evidence of treatment-related toxicity, and demonstrated that the HYAFF 11 film was degraded within 4 months. The Limulus Amebocyte Lysate (“LAL”) test is used to assess the pyrogenicity of HYAFF 11 as part of the finished product specifications, and the endotoxin levels are within specification (≤ 0.2 EU/mg).</p> <p>No toxicity was observed in USP XXII (Plastic Containers tests) testing, indicating that any potential leachable substances present in HYAFF 11 from the packaging used for HYALOMATRIX have no effect on the safety of this device.</p> <p>Biocompatibility testing on the Silastic® Medical Adhesive Silicone, Type A included cytotoxicity in multiple cell culture assays; pyrogenicity; U.S. P. Class V testing; hemolysis; 90-day implantation; and guinea pig skin sensitization. The material produced cytotoxic effects in multiple cell culture assays when placed in direct contact and when extracts of the material were tested. Pyrogenicity, U.S.P. Class V, and hemolysis assays were negative. Implantation studies with cured material resulted in no noteworthy histological findings, and saline extracts did not produce a skin sensitization response in guinea pigs.</p> <p>Biocompatibility testing on the Loctite cured film included intracutaneous irritation; acute toxicity; cytotoxicity; hemocompatibility; hemolysis; implantation; and U.S.P. physicochemical tests. The material was non-irritating, not acutely toxic; non-cytotoxic; non-hemolytic; hemocompatible; produced no treatment-related histopathological findings upon implantation; and passed the U.S.P. physicochemical tests.</p>
Performance Data:	Clinical experience HYALOMATRIX as a wound dressing supports the safety and effectiveness of the device.
Conclusions:	The performance data discussed above demonstrate that the device is as safe and effective, and performs as well as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Fidia Advanced Biopolymers S.r.l.
% Morgan, Lewis & Bockius, LLP
Sharon A. Segal, Ph.D.
1111 Pennsylvania Avenue, NW
Washington, District of Columbia 20004

Re: K073251
Trade/Device Name: HYALOMATRIX® PA
Regulation Number: Unclassified
Product Code: FRO
Dated (Date on orig SE ltr): November 19, 2007
Received (Date on orig SE ltr): November 26, 2007

Dear Dr. Segal:

This letter corrects our substantially equivalent letter of December 14, 2007.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark Melkerson", with a long horizontal flourish extending to the right.

Mark Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number K073251
(if known):

Device Name: HYALOMATRIX[®]

Indications for Use: HYALOMATRIX[®] is indicated for the management of wounds including: partial and full-thickness wounds; second-degree burns; pressure ulcers; venous ulcers; diabetic ulcers; chronic vascular ulcers; tunneled/undetermined wounds; surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence); trauma wounds (abrasions, lacerations, skin tears); and draining wounds. The device is intended for one-time use.

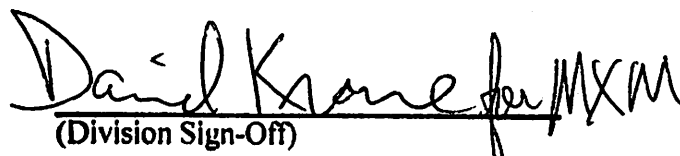
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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