SEP 2 9 2011

510 (k) Summary of safety and effectiveness

SUBMITTER INFORMATION

A.	Company Name:	M.V. s.r.l.
B.	Company Address:	Via F.lli Cervi, 7 Gonzaga (MN), Italy 46023
	Manufacturing facility:	Via Don G. Dossetti, 5/7 Gonzaga (MN), Italy 46023
	US Agent:	Laura Andreatta N. Devon Rd., Columbus, OH 43212, Phone +1-614-246-1141 Fax: +1-614-725-0890
C.	Company Phone: Company Fax: Company e-mail	+39 0376 536995 +39 0376 530441 info@mvsrl.it
D.	Contact Person:	Enrico Bisson Studio ingegneria Enrico Bisson
E.	Contact Phone: Contact Fax Contact E-mail	+39 0498630080 +39 0498630080 enrico.bisson@isoplan.org
F.	Date Summary Prepared:	February 28, 2011

DEVICE IDENTIFICATION

A.	Device name:	M.V. Intradermic Needles
B.	Trade/Proprietary Name:	M.V. Intradermic Needles
C.	Classification name:	Hypodermic Single Lumen Needle (21 CFR §880.5570)
D.	Product Code:	FMI

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

- ARTSANA HYPODERMIC NEEDLES, K051783

DEVICE DESCRIPTION

The device is comprised of a metal tube. On one end the tip is closed and blunt, while the cannula has an opening laterally at a lower point under the tip. On the other end the device is joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe.
The MV intradermic needle is marketed alone or combined with a pilot needle. The pilot needle is an hypodermic single lumen needle intended to prepare the site for injection. The tip of the pilot needle is sharpened at one end, while the other end is joined to a hub. The pilot needle can be any traditional legally marketed hypodermic needle.
The MV intradermic needles are single-use devices sold as sterile.

INTENDED USE

The MV intradermic needles are intended to inject fluids intradermally.

DISCUSSION OF NON CLINICAL TESTS

Following performance tests were performed on the MV Intradermic Needles to test their compliance with Recognized Consensus Standard ISO 7864 Sterile hypodermic needles for single use:

- Cleanness
- Acidity or alkalinity limits
- Limits for extractable metals
- Needle tube – Length requirements
- Needle tube - Absence of defects
- Execution - Hub/tube bond strength
- Execution - Evidence of lumen

None of the data raised any issues of safety and effectiveness. Additionally, a risk analysis was conducted according to Recognized Consensus Standard ISO 14971:2007.

Following biological tests were performed on the sterile final finished device to evalute biocompatibility:

- Cytotoxicity,
- Sensitization,
- Intracutaneous reactivity,
- Systemic toxicity
- Haemocompatibility.

None of the result of the tests arised any issues of biocompatibility.

SUBSTANTIAL EQUIVALENCE

The MV Intradermic Needles are same or similar in design, materials and intended use to the predicate devices. In further support of a substantial equivalence determination, Section 10 provides a comparison chart of the submitted device and the predicate devices. Main comparison element are as follows:

	MV INTRADERMIC NEEDLES	K051783
Intended / Indications For Use	The MN intradermic needles are intended to inject fluids intradermally.	To inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
Cannula material	AISI 304 Stainless Steel	AISI 304 Stainless Steel
Hub material	Polypropylene	Polypropylene
Needle diameter	22G, 25G, 27G, 30G; 21G, 23G, 26G, 27G	21G, 22G, 23G, 25G, 26G, 27G, 30G and more
Needle length (mm)	25, 27, 35, 37, 40, 50, 57, 70; 13, 25	13, 25, 40 and more
Tip configuration	closed blunt tip, lateral opening (intradermic needle), triple sharpened, non-coring (pilot needle)	triple sharpened, non-coring
Hub	color coded ISO 6009	color coded ISO 6009
Connection to syringe	Luer taper	Luer taper

Based on the available information, we conclude that the M.V. Intradermic Needles are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act. Therefore, the applicant device is determined as safe and effective.

SAMPLE

Sample of the MV Intradermic Needles is included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

M.V. S.R.L.
C/O Mr. Enrico Bisson
President
Studio di Ingegneria Enrico Bisson
Via Marzia 9
Abano Terme, Padova Italy 35031

SEP 29 2011

Re: K110606
Trade/Device Name: MV Intradermic Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 9, 2011
Received: September 16, 2011

Dear Mr. Bisson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110606

Device Name: MV intradermic needles

Indications for Use:

The MV intradermic needles are intended to inject fluids intradermally.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 9/28/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110606