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(949)366-2183

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TO: FREEDOM OF INFORMATION STAFF,HFZ-82
CENTER FOR DEVICES&RADIOLOGICAL HEALTH,FDA
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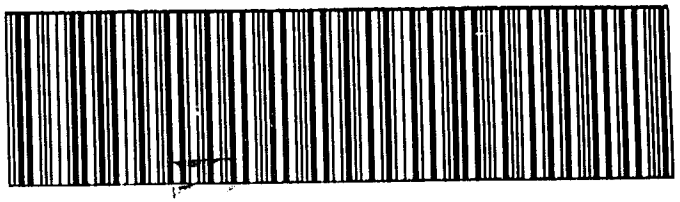

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Questions? Contact FDA/CDRH-FOISTAT@fda.gov or 301-796-9

K97085

97-2678

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

JUN 24 1997

Re: K970855
Trade Name: Clave Connector
Regulatory Class: II
Product Code: FPA
Dated: May 14, 1997
Received: May 19, 1997

Dear Ms. Dutchik:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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) 594-4618. 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 at (301) 443-6597.

Sincerely yours,

Patricia Cucinotta /for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12. Appendix C. Indications for Use

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

(Division Sign-Off) Patricia Cucinotta
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970855

Prescription Use ✓
(Per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 6/16/97

From: Reviewer(s) - Name(s) Irene Naveau

Subject: 510(k) Number K970855/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Accepted for review 5/21/97.
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☒NO
Is this device subject to the Tracking Regulation?	☐YES	☒NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☒NO
Is this a prescription device?	☒YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☒NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☒Enclosed
(required for originals received 3-14-95 and after)

☒A 510(k) summary OR ☐A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: 80/FPA/II/880.5440

Additional Product Code(s) with panel (optional):

Review: JOHN NAKAYAMA SUPVR (Branch Chief) HFZ-440 (Branch Code) 6/17/97 (Date)

Final Review: [illegible] (Division Director) 6/23/97 (Date)

Questions? Contact FDA/CDRH/OOC/DIM at CDRHFOISTATUS@fda.hhs.gov or 301-796-8118

Revised:11-20-96

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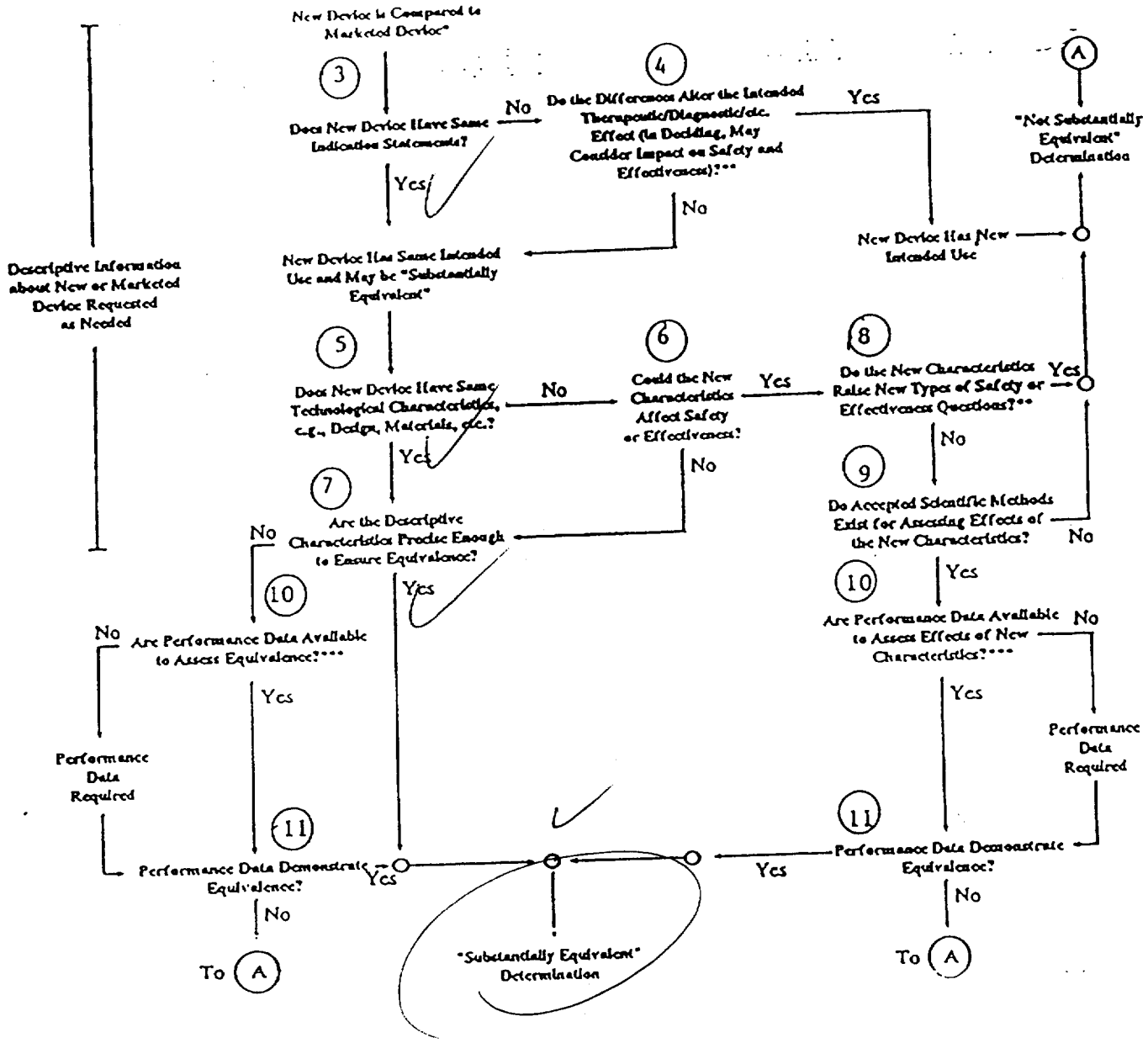
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- * 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

MEMO TO THE RECORD
510(K) REVIEW

K970855

DATE: June 16, 1997
FROM: Irene Naveau

OFFICE: HFZ-480
DIVISION:DDIG/GHDB

COMPANY NAME: ICU Medical Incorporated
DEVICE NAME: CLAVE Connector

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

ICU Medical Inc. has submitted this premarket notification to revise the existing intended use for this device to include the administration of fluids to a patient through a cannula placed in the artery. The intended use in the original 510k submission (K915571) for this device specified the administration of fluids into the patient's vein. Refer to telephone memo dated April 29, 1997 for more detail.

The CLAVE Needleless Connector is a sterile, one-piece, swabbable closed system designed to provide needleless access to the vein or artery of a patient. It may be used as a stand-alone device or as an accessory to an intravascular administration set for the administration of fluids to a patient. The valve allows for bi-directional fluid flow for administering fluid as well as for the withdrawal of blood for sampling. The fluid path is accessed by inserting a male luer connector into the female end of the connector. An internal silicone seal within the CLAVE Connector is depressed with the male luer, an internal piercing element pierces the silicone seal, and opens the fluid flow path. Upon removal of the luer fitting, the silicone seal springs back and reseals itself, thus stopping fluid flow.

The CLAVE Connector is not compatible with all male luers, therefore, the user should read the directions for use to obtain a listing of administration and pumps sets, extension sets and syringes/prefilled syringes with which this device is compatible.

Materials:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

2. INTENDED USE: The ICU CLAVE Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration sets for the administration of fluids to a patient through a cannula placed in the vein or artery.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: No
B. Implant (short-term or long-term): No
C. Is the device sterile? Yes
If yes, is sterility information included? Yes
D. Is the device for single use? Yes
E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes

F. Is the device for home use or portable? Yes
G. Does the device contain drug or biological product as a component? No
H. Is this device a kit? No
I. Software-driven: No
J. Electrically Operated: No

K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): ANSI/AAMI/ISO 11135 (EtO sterilization); AAMI (gamma sterilization)

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: SmartSite Needle Free Valve Administration Sets, IVAC Medical Systems, K960280.

M. Submission provides

comparative specifications	a	Yes
comparative in vitro data	b	No
performance data	c	Yes
animal testing	d	No
clinical testing	e	No
biocompatibility testing	f	No

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The CLAVE Needleless Connector is identical to the CLAVE Needleless Connector originally cleared under 510k K915571. It is similar to the SmartSite in that both are needleless devices with one piece designs activated by luer connections to allow bi-directional fluid flow. The intended uses are similar with on exception, the CLAVE Needleless Connector includes access to an artery.

Performance testing conducted on this device included the fluid flow, leak retention, leak pressure, lipid reactivity, and negative pressure resealability. Refer to section 4.3, for comparative performance testing with the CLAVE Connector and the SmartSite. Microbial challenge studies were not conducted for this submission but on the original CLAVE Connecter (K915571) and this device is identical to the original device. Microbial challenge studies are not, therefore, required for this submission.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

Sterilization for this device will include ethylene oxide or gamma radiation. Sterilization with ethylene oxide will be validated in accordance with ANSI/AAMI/ISO 11135, and achieve a sterility assurance level of 10^{-6}. Maximum residue levels for ethylene oxide, ethylene chlorohydrin, and ethylene glycol are 25 ppm, 25 ppm, and 250 ppm respectively. Sterilization by gamma will be validated according to AAMI Method 1, and will achieve a sterility assurance level of 10^{-6}. Radiation dose will be 2.5 to 4.0 megarads. Testing for pyrogenicity will be the LAL method. Packaging will consist of a form-fill sealed thermoplastic pouch and waxed paper lidding material. The lower material is a fiber-free clear film (StarTex C-Film), and the lidding material (Oliver 29Hp-10)is a fiber fill peelable paper.

ICU Medical, Inc. certifies that..."the materials used to manufacture the CLAVE Needleless Connector are exactly the same as in the devices that are currently marketed in interstate commerce" under comparable conditions of use. However, section 7.1 consists of material biocompatibility information stating that the internal conduit, housing, silicone seal, and lubricant have all passed Tripartite evaluation.

The labeling for this device is adequate and includes appropriate caution statements, recommended time of use, directions for use which include drawings, and promotional literature.

Based on the information provided in this premarket notification, I believe that this device is as safe and effective as similar legally marketed devices. No new issues of safety and effectiveness exist for this device. I believe that this device is identical to the original CLAVE Needleless Connector, as stated above and is substantially equivalent to the SmartSite Needle Free Valve Administration Set, IVAC Medical systems.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FPA

Classification should be based on: (Accessory) Intravascular Administration Set

880.5440 Class: II

Irene Naveau 6/16/97

Irene Naveau

VOK 6/12/97

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K970855

Reviewer: Irene Naveau

Division/Branch: DDIGD/GHDB

Device Name: CLAVE Connector

Product To Which Compared (510(K) Number If Known): SmartSite Needle Free Valve Administration Sets, IVAC Medical Systems, K960280

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?		X	If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If **YES** = Stop **NE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The ICU CLAVE Needleless Connector is a single use, sterile, non pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

2. Device Description: See SE memo dated June 16, 1997.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. How does the new indication differ from the predicate device's indication: The new indication included administering fluids via the artery, whereas the indication for the predicate device states that the device is administered intravenously, only.

4. Explain why there is or is not a new effect of safety or effectiveness issue: Sufficient data was obtained to demonstrate that there is no new safety or effectiveness issues for this device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 20, 1997

ICU MEDICAL, INC.
951 CALLE AMANECER
SAN CLEMENTE, CA 92673
ATTN: ARLENE DUTCHIK

510(k) Number: K970855
Product: CLAVE CONNECTOR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K970855 13

ICU Medical, Inc.

RECEIVED
19 MAY 97 12 07
FDA/CDRH/OCE/DID

May 14, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Attention: Document Control Clerk

RE: K970855 - Revise Intended Use for Clave Connector
Response to request for additional information

This is in response to your request for additional information regarding the above submission. As per our phone conversation on 4/29/97, listed are the requested items for revision:

- Omit abdomen in the intended use statement, through out entire submission
- Revise labeling to include 24 hour change or per validated facility protocol, Appendix A & B
- Include chemical name for device materials, section 6.1
- Description of device, section 6.1
- Remove tripartite and insert ISO 10993, section 7.1
- Back pressure on arterial line must show testing of pressure testing greater than normal systolic pressure 200-250 mmHg, sections 4.3 and 4.4

The Clave Needleless Connector was originally cleared in ICU Medical, Inc. 510(k) K915571.

I believe that the information in this revised submission meets all of your requests. If you have any questions or concerns, please contact me at (714) 366-2183 x-319.

Regards,

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8368

951 Calle Amanecer - San Clemente, CA 92673 • (714) 366-2183 • (800) 824-7890 • Fax (714) 366-3368

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ICU Medical

510(k) Notification

Clave Connector

Trade Name:	Clave Connector
Manufacturer:	ICU Medical Inc. 951 Calle Amanecer San Clemente, CA, 92673
Registration Number:	2025816
Classification Name:	IV Administration Set, (80 FPA) Clave Connector
Regulatory Class:	II
510 (k) Number:	K970855
Submitted By:	ICU Medical Inc. 951 Calle Amanecer San Clemente, CA, 92673
Contact Person:	Arlene Dutchik
Contact Phone:	714-366-2183
Contact Fax:	714-366-8368

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

1. GENERAL INFORMATION

1.1. Applicant

Date: May 14, 1997
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714) 366-2183

Signature: Arlene Dutchik

1.2. Trade Name
Clave Connector

1.3. Common Name or Classification Name
Intravascular Administration Set

1.4. Establishment Registration Number
2025816

1.5. Facility Address

Manufacturer Address
ICU Medical Inc.
951 Calle Amanecer
San Clemente, CA 92673

Contract Sterilizer Address
Isomedics
43425 Business Park Dr.
Temecula, CA 92590
Registration Number: 2030624

Sterigenics International
344 Bonnie Circle
Corona, CA 91720
Registration Number: 2029275

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.6. Section 513 Device Classification

1.6.1. Classification
Devices of this type have been classified as Class II medical device per 21 CFR 880.5440, Intravascular Administration Set (80FPA).

1.7. Reason for Premarket Notification
Revise the intended use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

1.8. Predicate Device Description

1.8.1. Name
IVAC Needle Free Valve Administration Sets (SmartSite™)

1.8.2. Predicate Device Company
IVAC, Inc.

1.8.3. Predicate Device 510(k)#
K960280

1.9. Special Controls/Performance Standard Compliance
ICU Medical Inc. knows of no published standard(s) pursuant to the requirements of Section 514 of the Act that are applicable to this product.

2. STATEMENT OF INTENDED USE

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

3. DEVICE LABELING

3.1. Device Labels
Carton Label (see Appendix A)
Primary Package Label (see Appendix A)

3.2. Labeling
Instructions for use are printed on the Primary Package (see Appendix B).

3.3. Advertising
Promotional Material (see Appendix D).

4. SUBSTANTIAL EQUIVALENCE INFORMATION

4.1. Equivalent Device Information

Name: IVAC Needle Free Valve Administration Sets (SmartSite™)
Status: Currently in commercial distribution
510(k) #: K960280

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4.2. Comparative Information

Characteristic Compared	CLAVE® NEEDLELESS CONNECTOR	IVAC NEEDLE FREE VALVE ADMINISTRATION SETS (SMARTSITE™)
Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needleless injection port to access any vein or artery.	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silicone Rubber Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

4.3. Comparative Performance Testing

PERFORMANCE CHARACTERISTIC	CLAVE® NEEDLELESS CONNECTOR (Avg. / Std)	IVAC NEEDLE FREE VALVE ADMINISTRATION SETS (SMARTSITE™) (Avg. / Std)
Fluid Flow (ml/min.):	176.6 / 17.8	114.6 / 22.0
Luer Retention (lbf)	11.7 / 1.7	11.5 / 3.0
Leak Pressure (psig)	23.5 / 1.1	57.4 / 17.3
Lipid Reactivity	No cracking after 72 hours	No cracking after 72 hours
Negative Pressure Resealability	-9.5 psig	Unknown

4.4. Comparative Information

Sample Size Justification: sample sizes were selected to provide sufficient data points for calculation statistical parameters.

Sample size of n=60 for the ICU device was selected to provide sufficient data points to define a distribution of performance values.

Sample size of n=12 for the SmartSite device was selected due to limited access of competitor device.

Testing Methodologies:

1. (b)(4) [redacted]
2. Luer Retention: samples were tested by inserting a male luer slip [redacted] proximal end port of the test sample at 5.5 lbs. insertion force and 90° twist using push/pull force gage. Verify luer slip is retained in the test sample. [redacted]
3. (b)(4) [redacted]
4. [redacted]
5. [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

4.5. Change or Modification Information

Revise the intended use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

5. PREDICATE DEVICE LABELING

5.1. Labels

Predicate device labeling and Directions for use is included in Appendix I.

5.2. Advertising and Promotional Materials

Predicate device advertisement and promotional material is included in Appendix J.

6. DEVICE SPECIFICATIONS

6.1. Description and Engineering Drawings

The Clave Connector is a needleless, one piece, swabable, closed system. It is designed to preclude the use of needles for lumen access. The Clave Connector is single use, sterile and non pyrogenic device intended for use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

A Standard male luer (device or needleless syringe) can be connected and locked into place within the female end of the Clave Connector. An internal silicone seal within the Clave Connector is depressed upon insertion of the male luer fitting below the openings of the plastic conduit, thereby permitting fluids to flow through these openings. Upon removal of the luer fitting by counter-clockwise rotation of the luer device, the silicone seal springs back well above the level of the plastic internal conduit, resealing it and stopping fluid flow.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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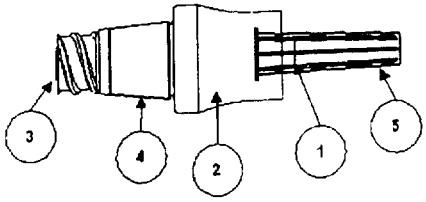
ICU Medical Inc.
CLAVE CONNECTOR

The Clave Connector is provided sterile, in medical device grade components:

	Component	Generic Name	Chemical Name	Manufacturers Name
1.	Internal Conduit	(b)(4) [redacted]		
2.	Housing			
3.	Silicone Seal			
4.	Ring			
5.	Breather Cap			
6.	Lubricant			



22

(b)(4)

[redacted]

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6.2. Voluntary Standards Conformance

There are currently no mandatory FDA Performance Standards for Intravascular Administration Sets.

7. MATERIAL/BIOCOMPATIBILITY INFORMATION

7.1. Patient Contacting Materials

Component Description	Material	Contact Category/Duration	ISO 10993 Evaluation
Internal Conduit	(b)(4) [redacted]	Blood Path Indirect/Prolonged	Pass
Housing		Blood Path Indirect/Prolonged	Pass
Silicone Seal		Blood Path Indirect/Prolonged	Pass
Lubricant		Blood Path Indirect/Prolonged	Pass
Breather Cap		Non-Contact Device	N/A
Ring		Non-Contact Device	N/A

8. STERILIZATION INFORMATION

The CLAVE Connector is provided sterile. The CLAVE Connector may be sterilized using radiation or ethylene oxide.

8.1. Sterilization Method

RADIATION
Radiation Dose: 2.5 to 4.0 megarads

8.1.1. Validation Method

The methods used to validate the sterilization cycle for the devices are based on the practices recommended by the Association of the Advancement of Medical Instrumentation (AAMI), Process Control Guidelines for Radiation Sterilization of Medical Devices (1991), Method 1. Pre sterilization Bioburden levels will be determined based upon Bioburden testing conducted on 10 samples for each of 3

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different production lots. Bioburden testing will be conducted by a contract laboratory per established procedures. The mean and standard deviation of the CFU counts of the test samples will be reported. A Sub-process dosage shall be identified using Table 7 in the AAMI Process Control Guidelines for Radiation Sterilization of Medical Devices (1991), Method 1. The verification dose representing an SAL = 10^{-2} for the bioburden level shall be identified as the Sub-process dosage. A minimum of 100 samples shall be exposed to the Sub-process dosage(± 0.1 megarad or ± 10%, whichever is greater).

Successful completion of the verification dose exposure requires recovery of no more than two (2) positive cultures from a minimum of one hundred(100) products treated at that dose.

This validated dosage shall be audited 4 times per year to assure continued suitability.

8.2. Sterilization Method: ETHYLENE OXIDE

8.2.1. Validation Method

Devices will be sterilized the with ethylene oxide to achieve a sterility assurance level of 10^{-6}. The sterilization load must be validated to assure adequate aeration to achieve residual level of ≤ 25 ppm for EtO and EtCH: the residuals level for EtG will be ≤ 250 ppm. The sterilization cycle is validated in accordance with the requirements of ANSI/AAMI/ISO 11135, "Medical Devices, Validation and Routine control of Ethylene Oxide Sterilization. The half cycle approach consists of a total three (3) fractional half time exposures and (3) full time exposure runs. Cycle parameters are selected following a review of the product/packaging characteristics including complexity of the product resistance to permeation of the sterilant gas, permeation properties of the packaging, bioburden level, product density when palletized and the desired SAL (10^{-6}) to be achieved. Sublethal exposure runs utilizing graded population spore strips embedded into the documented reference product will be run. Fractional positive/negative response will be used to document the

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comparative resistance of Biological Indicator (BI) challenge configurations and finished product. Comparative resistance data will be used to support the appropriateness of the BI system employed and to verify the sensitivity of the sterility test methods selected.

8.3. Sterility Assurance Level (SAL)

The device shall meet a Sterility Assurance Level (SAL) of 10^{-6} when sterilized using either sterilization method (radiation or ethylene oxide).

8.4. Sterile Packaging Description

The device uses a form-fill-seal thermoplastic pouch and waxed paper lidding material. The bottom material (StarTex C-Film) is a fiber-free clear film. The lidding material (Oliver 29HP-10) is a fiber-free, peelable paper lidding that provides a strong, breathable substrate.

8.5. Pyrogen Testing

Each product lot shall be tested using Limulus Amebocyte Lysate (LAL) Testing. Testing is performed by a contract laboratory following the guidelines set forth by the Food and Drug Administration in Guidelines on Validation of the Limulus Ameboytte Lusate Test as End Product Endotoxin Test of Human and Animal Parental Drugs, Biological Products and Medical Devices (1987).

This device is not intended for sterilization or reuse/re sterilization by the user.

9. SMDA INFORMATION

9.1. 510(k) Summary

A 510(k) Summary is included in the appendix H.

9.2. Truthful / Accurate Statement

A Truthful and Accurate Statement, as required by 21 CFR 807.87(j), is provided in the Appendix E.

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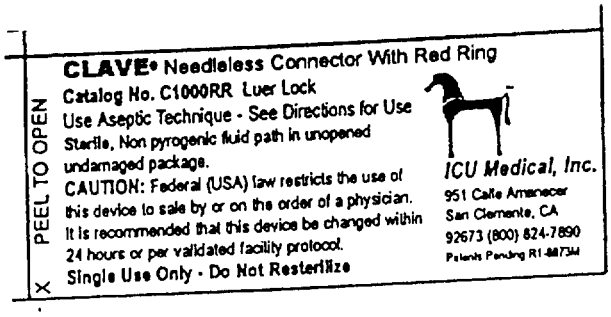
10. Appendix A. Device/Packaging Labeling

DEVICE LABEL



MASTER CARTON LABEL

ICU MEDICAL, INC.
(800) 824-7890
CATALOG NUMBER C1000RR
CLAVE CONNECTOR WITH RED RING
STERILE - 100
LOT NUMBER: XXXXX

R1-XXX

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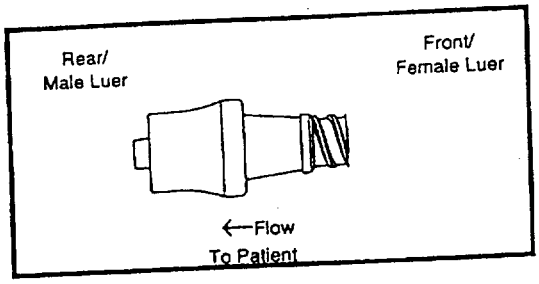
11. Appendix B. Directions for Use

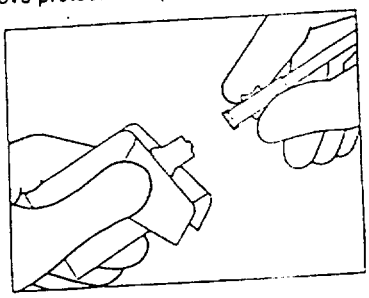
PROPOSED DIRECTIONS FOR USE TEXT

CLAVE® Needleless IV Connector
Catalog No. C1000, C1000G & C1000RR

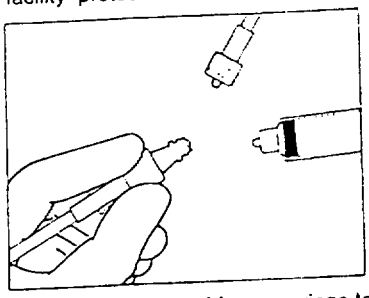


DIRECTIONS FOR USE

1. Peel open package at designated end and remove protective cap. Use Aseptic Technique.



2. Attach luer of catheter or extension set to rear of CLAVE Connector. Prime per facility protocol.
3. Swab silicone seal on top of CLAVE Connector per facility protocol. **Do Not Contaminate.**



4. Attach male end of IV tubing or syringe to CLAVE Connector. To secure - push and twist until tight. **Do Not Use Needles.**
5. To disconnect, twist IV connector or syringe until loose and pull apart. Do not remove CLAVE Connector from patient's catheter or tubing.
6. Flush CLAVE Connector after each use per facility protocol.
7. CLAVE Connector is closed. No capping is necessary.
8. To reconnect, repeat from step 3.

The CLAVE Connector is compatible with the following devices containing male luers. (As of Nov. 1995)

ADMINISTRATION AND PUMP SETS (All Standard bore sets)

Abbott Laboratories*
Codan Medlon
McGaw, Inc.
3M
Baxter
IMED
Medex
Block
Churchill Medical Systems
IVAC
MPS
Secure

* Except Energizer and Snap Dose sets

EXTENSION SETS (Standard bore and Minibore sets)

Abbott Laboratories
IVAC
Medex
Advanced Medical Devices
Codan Medlon
Baxter
IMED
3M
Churchill Medical Systems
McGaw, Inc.
Summit Medical

BC 591 Minibore, M/F LL, clamp, 7"

MPS

EG-060-01 Minibore, M/F LL, clamp, 60"

EXTENSION SETS (Microbore sets)

Summit Medical
Advanced Medical Devices

Baxter

IM8516 Ultra-Microbore, M/F LL, filter, clamp, 60"
IM8522 Ultra-Microbore, M/F LL, filter, clamp, 60"
IM8521 Microbore, M/F LL, 36"
IM8511 Ultra-Microbore, M/F LL 60"
IM6510 Ultra-Microbore, M/F LL, 36"

MPS

EA-060-05 Ultra-Microbore, M/F LL, filter, 60"
EA-060-01 Microbore, M/F LL, clamp, 60"
EA-060-01 Ultra-Microbore, M/F LL, 36"
EB-060-01 Microbore, M/F LL, clamp, 60"
EG-060-01 Minibore, M/F LL, clamp, 60"

Churchill Medical Systems

AMS-761 Microbore, M/F LL, clamp, 7"
AMS-437 Microbore, M/F LL, clamp, 36"

SYRINGES/PREFILLED SYRINGES

Abbject Monoject
Terumo
Carpuject (with ICU Medical's CS-20)
Solopak
Becton Dickinson (BD)

CAUTION: The CLAVE Connector is not compatible with every device containing male luers. DO NOT use any device containing a male luer with the CLAVE Connector unless it is on the above list o you have received written verification of its compatibility from ICU Medical. Please call (800) 824-7890 for verification.

Sterile, Non-Pyrogenic fluid path in unopened, undamaged package.

DO NOT USE NEEDLES
SINGLE USE ONLY - DO NOT RESTERILIZE
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

It is recommended that this device be changed within 24 hours or per validated facility protocol.

ICU MEDICAL, INC.
951 Calle Amanecer
San Clemente, CA 92673
(714) 366-2183 (800) 824-7890
Patents Pending

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12. Appendix C. Indications for Use

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13. Appendix D. Promotional Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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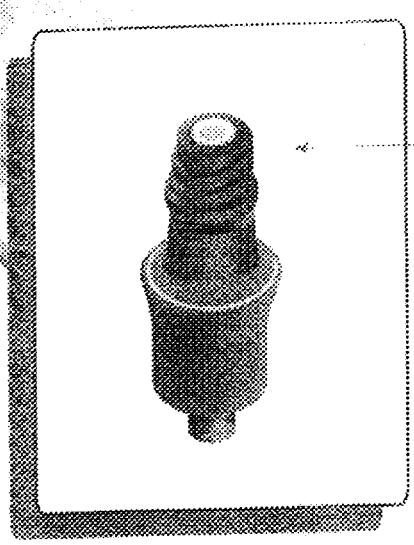
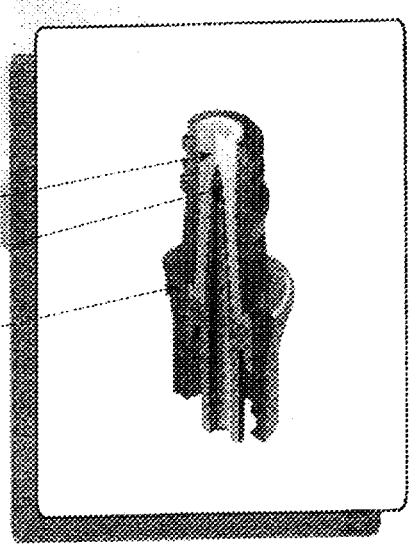
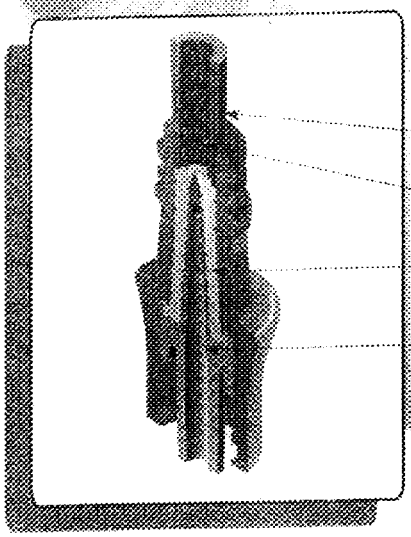
The CLAVE™ Connector



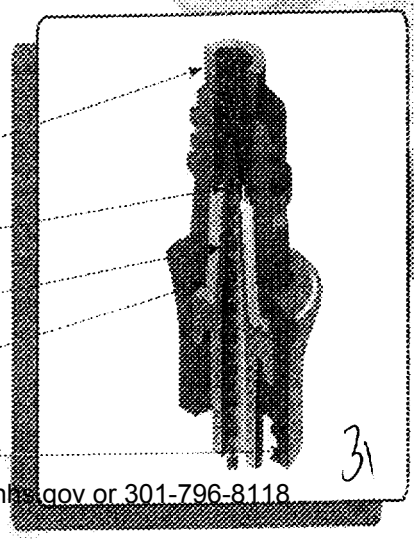
The Clave Connector



Compression Seal
Internal Piercing Element
Coupling Lock



Luer Tip
Fluid
Compression Seal
Internal Piercing Element



Luer Tip
Fluid Flow
Internal Piercing Element
Compression Seal
Coupling Lock

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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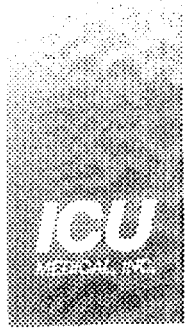
CLAVE™ CONNECTOR

Simple safety that forces compliance...



One Piece, Swabable, Needleless IV connecting device that forces compliance with hospital's needle free policies.

Why go to the added expense of implementing a needleless system that permits the use of needles?

With the Clave™ Connector, *Needleless means No Needles.*

FORCED COMPLIANCE...means no more needlesticks from IV connections.

Don't allow needlesticks to continue with your needleless connector.

No needle means no needlesticks.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1-800-824-7890

M1-1023 7/96

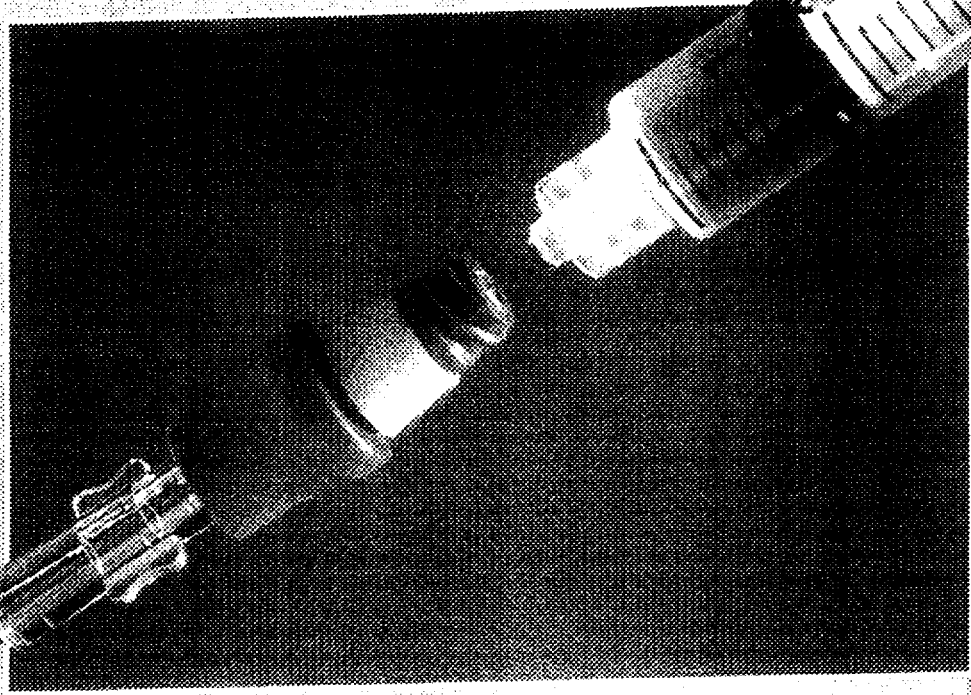
Freedom of Information Act FDA Request # 2010-2140 Released by CDRH on 11-22-2011

Clave™ Connector

One Piece, Needleless Connector.

One Trip, to the bedside.

One Charge, to the patient.



SIMPLE SAFETY THAT FORCES COMPLIANCE.

The Clave® is the only one piece, swabable, needleless IV connector that will not permit needle access and does not require caps or cannulas.

•

WHY SPEND MONEY ON A NEEDLELESS SYSTEM THAT PERMITS THE USE OF NEEDLES?

Needleless should mean...No Needles. Engineered to eliminate IV related needles and needlesticks, the Clave® does not permit the use of needles thereby forcing compliance with current needle-free policies.

•

NEEDLELESS SHOULD MEAN...NO NEEDLESTICKS.

951 Calle Amanecer
San Clemente, CA 92673
(714) 366-2183

ICU
ICU Medical, Inc.
Toll Free (800) 824-7890

Questions? Contact FDA/ODRH/OCE/DIC at 301-594-4591 FAX 301-594-4732 or dic@cdrh.fda.gov or 301-796-8118

M1-1014

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14. Appendix E. Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as Regulatory Affairs Specialist of ICU MEDICAL, INC. I believe to the best of my knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

Signed: Arlene Dutchik
Name: Arlene Dutchik
Position: Regulatory Affairs Specialist
Date: May 14, 1997

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15. Appendix F. Microbial Challenge Study

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXPERIMENTAL MICROBIAL CHALLENGE AND DECONTAMINATION OF CLAVE™ CONNECTORS

PAUL A. GIBILISCO, M.D., F.A.C.P., F.A.C.R.

GREGORY S. PAGE

Objective: *To ascertain whether a closed system, needleless IV device, the Clave™ Connector, when microbiologically challenged, can be thereafter decontaminated with 70% Isopropyl Alcohol and maintain a sterile barrier.*

Design: *Experimental protocol simulating clinical practice.*

Setting: *Contract Quality Assurance GLP/GMP Microbiology Laboratory, Laboratory Services, Monrovia, CA.*

Challenge Organism: *Pseudomonas aeruginosa : in the first experiment, the nominal population of the inoculum utilized was 1.0 x 10^3/ml; and in the second experiment, the nominal population of the immersion pool was a 1.0 x 10^4/ml suspension. Note: Pseudomonas aeruginosa was chosen for its motility.*

Results:

- *No positive cultures of Pseudomonas aeruginosa were observed following each of the 20 activations of the inoculated and thereafter decontaminated Clave™ Connectors.*
- *No positive cultures were observed in Clave™ Connectors after a continuous 72 hour engagement period, followed by an additional 19 activations and immersion into a 1 .0 x 10^4 /ml nominal population suspension. Also, in the last phase of this experiment, no growth was observed in any of the test units after their void area was pressure filled from their male luer with sterile SCDB media.*

Conclusions:

- *Experimental contamination of the Clave™ Connector with Pseudomonas aeruginosa at its female luer was undertaken with repeated activations, and effective decontamination of the Clave™ Connector was achieved in 100% of the devices tested.*
- *After multiple and prolonged activations, the Clave™ Connector was able to maintain its sterile barrier when challenged by immersion into a 1.0 x 10^4 /ml nominal population suspension of Pseudomonas aeruginosa.*

Materials and Methods:

The following materials were used in this contamination study of the Clave™ Connector: Sterile test systems (Figures 1 and 2) including- Sterile Clave™ Connectors (ICU Medical, Inc., San Clemente, CA), sterile female to female luers, and sterile 10cc syringes (Becton Dickinson, East Rutherford, NJ); class 100 laminar flow hood, culture loops, sterile swabs, 58 x 138mm sterile screwcap jars, incubators (30-35° C and 20-25° C), a Vortex mixer, sterile 18 gauge needles, sterile gloves, alcohol wipes, sterile Pipets, 3000ml Aspirator bottles, sterile cleanroom garments, classroom 100 cleanroom, Bunson Burner, sterile Phosphate buffered water, water bath, Biological cabinet, and a centrifuge.

The following sterile Nutrient Media was used in this study: 1) Soybean Casein Digest Broth (SCDB), steam sterilized at 121° C, post sterilization pH 7.3 ± 0.2 @ 25° C, aseptically filled into sterile 10cc syringes, 2) Soybean Casein Digest Agar (SCDA), steam sterilized at 121° C, post sterilization pH 7.3 ± 0.2 25° C, poured into 150 x 15mm Petri dishes. The challenge microorganism used in this study was Pseudomonas aeruginosa, ATCC #15442 (Culti- loop®), titered to nominal populations of 1.0 x 10^4 spores/ml and 1.0 x 10^3 spores/ml.

Preparation

In a Class 100 LAF hood located within a class 100 cleanroom, 1920 individual syringes were aseptically filled with 10ml of the sterile SCDB from 3000ml aspirator bottles. The stainless steel luer adapters of the aspiration tubes were flame sterilized between each syringe fill. The syringes were incubated at 30-35° C for 72 hours and observed for signs of bacteria growth to verify the sterility of the units prio to use. A sterile 15ml tube of SCDB wa preheated to 45° C in a waterbath, and a Cult Loop® package was opened in a biologic cabinet with the loop placed into preheate media until gelatin was rehydrated into th media. Four 1ml aliquots of suspension wer transferred to separate 15 x 150mm SCDA Pet dishes and incubated for 24-48 hours. Afte incubation, the cells were harvested from 5 to isolates and placed into separate centrifuge tube each placed into a centrifuge and run at minimum of 1000 rpm for 15 minutes. Debr was aseptically removed using a sterile pipet and this process was repeated until all debris w removed. Serial dilutions were performed enumerate suspensions and test suspensions we prepared at nominal populations of 1.0 x 10^4 /n and 1.0 x 10^3 /ml. The final population suspensions was verified prior to use.

Decontamination Evaluation

The test articles were labeled follows: Clave™ Test group (20 ea.) = B1-B2 Clave™ Test group positive control (2 ea.) B21 & B22, Clave™ Test group negative contr (2 ea.) = B23 & B24, and Clave™ Populatic verification samples (3 ea.) = PV1-PV3. Tl sterile test systems were removed and attached Clave™ Connectors; then the septum of ea Clave™ Connector was swabbed with separa swabs impregnated with a nominal populatic 1.0 x 10^3 /ml suspension of Pseudomon aeruginosa, and allowed to dry at roo temperature. Following standard hospi procedures, repeated use simulation was beg by decontaminating each Clave™ Connect using alcohol prep pads (saturated with 70 isopropyl alcohol), and fully engaging each u with separate 10 ml SCDB filled syringes. Ea contaminated port of entry was swabbed o one time with only one prep pad. Media w pushed through the connectors and collected the distal IV luer using separate sterile 1C syringes. Sterile female luer connectors w used to connect the male luer of each Clav Connector to these sterile syringes. The syrin were capped and labeled, and incubated at 30-3 C for seven days. The test units w decontaminated and engaged for a total of replicate use simulations per unit, and cultu after each product engagement. The negat control samples were processed as test un omitting the challenge organism s procedure. The positive control samples w processed as test units omitting standard hospi decontamination procedures. Follow incubation, all test cultures were observed visible turbidity and results were recorded as (or (-) for bacterial growth. All positive gro was subcultured and presumptively identified confirm the presence of challe microorganism. Population verification performed on units identified as PV1 - PV3.

Sterile Test System

Figure 1

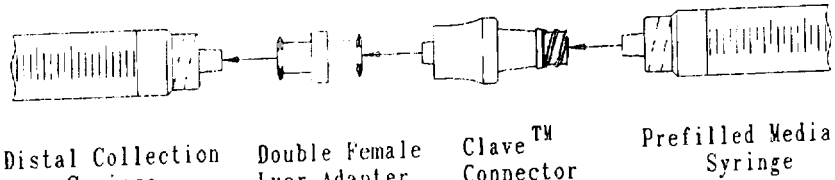
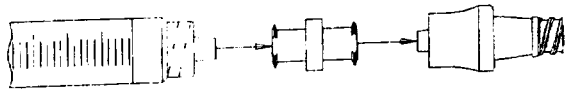


Figure 2



Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOLSTATUS@fda.hhs.gov or 301-796-8118

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Table I

																					Positive Controls		Negative Controls	
	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12	B13	B14	B15	B16	B17	B18	B19	D20	B21	B22	D23	B24
1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	20/20	20/20	0/20	0/20

Microbial Challenge

The test articles were labeled as follows: Clave™ Connectors (20 ea.) = D1-D20 group, Clave™ Connector positive controls (2 ea.) =D21 & D22 group, and Clave™ Connector negative controls (2 ea.) =D23 & D24 group. Sterile test systems were attached to Clave™ Connectors. The Clave™ Connectors were decontaminated and engaged with 10cc SCDB filled syringes, and the test systems were primed. The syringes remained connected to the Clave™ for 72 hours. Following the initial 72 hour engagement period, the syringes were removed after flushing, and the media was collected at the distal Luer using a separate sterile 10cc syringe. Nineteen additional short term engagements were performed, each preceded by decontamination procedures, and systems were flushed with each engagement. Following the 20 decontamination/engagements of each unit, the Clave™ units were immersed for 90 seconds in a nominal 1.0 x 10^4 /ml culture of Pseudomonas aeruginosa , and allowed to dry at room temperature. The test systems were then decontaminated and incubated for 24 hours at 30-35° C. Following incubation, media inside the systems was aseptically transferred to separate 100ml SCDB jars and incubated for an additional 7 days at 30-35° C. A separate SCDB filled syringe was aseptically connected to each test system (see Figure 2). The Clave™ was pressurized from the distal SCDB filled syringe with sufficient pressure to fill the void between the silicone boot and spike conduit with media. The syringe barrel was immobilized using a flame sterilized 18 gauge x 2 1/2 hypodermic needle as a cotter pin. The system was incubated with SCDB filled void for 7 days at 30-35°C. The negative controls were processed as test samples, omitting immersion in challenge microorganism. The positive controls were processed as test samples after the reseal was enlarged with 18 gauge needles and observations of droplet formations due to exerted pressure were noted on raw data sheets. Following incubation, results were recorded as (+) or (-) and all bacterial growth was presumptively identified to confirm the presence of challenge microorganism.

Results:

In the first experiment (Table I), all positive controls were culture positive within 72 hours of incubation. All test units of Clave™ Connectors were culture negative after 7 days of incubation including the negative controls. The 20 inoculated and decontaminated Clave™ Connectors were cultured after each subsequent activation (up to 20 activations) and no Pseudomonas aeruginosa growth was observed.

In the second experiment, Parts A and B, and all positive controls were culture positive within 72 hours of incubation, and all negative controls were culture negative after 7 days of incubation. In Part A (Table II), no positive culture of Pseudomonas aeruginosa was observed in any of the 20 Clave™ Connectors after a 72 hour engagement period, followed by 19 additional activations. In Part B (Table III), these 20 Clave™ Connectors were aseptically connected at the male luer via a sterile female to female connector to a separate sterile SCDB filled syringe (Figure 2). Sufficient pressure was exerted to fill the void between the silicone boot and spike conduit to ensure that the SCDB completely filled the void area. Enough pressure was exerted such that SCDB droplet formations were observed on 7 of the 20 Clave™ Connectors. Each syringe barrel was then immobilized. No Pseudomonas aeruginosa growth was observed in any of the SCDB cultures taken from the male end of each Clave™ Connector after a 7 day incubation period.

Conclusions:

These experiments were designed to test the integrity of a closed system, one-unit, needleless device, the Clave™ Connector, by challenging this device with Pseudomonas aeruginosa. In the first experiment, effective decontamination of the female luer was demonstrated when the inoculated Clave™ Connectors were swabbed with 70% isopropyl alcohol and no positive cultures were observed after repeated activations.

In the second experiment, 20 additional test systems of Clave™ Connectors were activated for a 72 hour period, followed by 19 additional activations. Then, the prefilled media syringes were removed and the Clave™ Connectors were immersed into a 1.0 x 10^4 /ml nominal population suspension of the Pseudomonas aeruginosa. No growth of Pseudomonas aeruginosa was observed in any of the Clave™ Connectors tested. This demonstrates that the Clave™ Connector is able to maintain its sterile barrier following prolonged and multiple activations. In Part B of this experiment, the same Clave™ Connectors were pressure filled with SCDB from their male luer end and incubated for 7 days. No growth of Pseudomonas aeruginosa was observed after this 7 day incubation period. This demonstrates that the Pseudomonas aeruginosa was not able to ingress into the void area between the silicone boot and the spike conduit.

These experiments reveal that the Clave™ Connector is an effective, one-unit, closed system, IV device that resists microbial growth at its female luer end. Effective decontamination of Clave™ Connectors was achieved in 100% of the devices tested and no Pseudomonas aeruginosa was isolated from any Clave™ Connector after its internal integrity was challenged for microbial growth.

Table II

Product #	Result	Product	Result
D1	(-)	D11	(-)
D2	(-)	D12	(-)
D3	(-)	D13	(-)
D4	(-)	D14	(-)
D5	(-)	D15	(-)
D6	(-)	D16	(-)
D7	(-)	D17	(-)
D8	(-)	D18	(-)
D9	(-)	D19	(-)
D10	(-)	D20	(-)
Pos Control D21		(+)	
Pos Control D22		(+)	
Neg.Control D23		(-)	
Neg.Control D24		(-)	
Total (+) test units / # units		0/20	

Table III

Product #	Result	Product	Result
D1	(-)	D11	(-)
D2	(-)	D12 *	(-)
D3 *	(-)	D13 *	(-)
D4	(-)	D14	(-)
D5	(-)	D15	(-)
D6 *	(-)	D16 *	(-)
D7 *	(-)	D17	(-)
D8	(-)	D18	(-)
D9	(-)	D19 *	(-)
D10	(-)	D20	(-)
Pos Control D21		(+)	
Pos Control D22		(+)	
Neg.Control D23		(-)	
Neg.Control D24		(-)	
Total (+) test units / # units		0/20	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

Contamination and Decontamination Study for the IVAC® SmartSite™ Needleless System

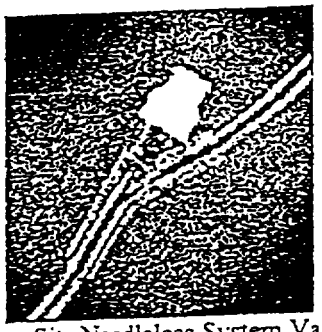
Wayne J. Rogers, Principal Investigator
Material Safety, Sterility Assurance and Environmental Affairs

Eleanor L. Fitzgerald, RN, BSN
Senior Clinical Study Specialist

Overview

A study was conducted to demonstrate the capability of the SmartSite capless valve to resist bacterial contamination through the valve after repeated inoculations with *Staphylococcus aureus*. The ability to effectively decontaminate the valve with 70% isopropyl alcohol was also tested.

As reported by the ECRI Health Devices publication on needlestick prevention, needleless devices are designed to reduce needlestick injuries and subsequent exposure to infected blood by decreasing the use of needles for IV administration. The SmartSite needleless system's unique valve design is intended to resist bacterial contamination through the valve by maintaining a closed system when not activated. The SmartSite needleless valve is activated with any standard luer lock or luer slip syringe, secondary IV set or other IV products. The valve opens when a luer end is inserted into the valve port and reseals when removed, thus preventing fluid flow after administration is complete.



SmartSite Needleless System Valve

Procedure

To validate the capability of this needleless valve to resist bacterial contamination of an IV administration set and to be effectively decontaminated, Silliker Laboratories of California, Inc., Carson, CA, conducted an independent in vitro laboratory study. As required by the United States Pharmacopoeia (USP) for sterility testing, a sample size of 20 SmartSite valves were tested. The valves were inoculated once every 24 hours with pathogenic *S. aureus* during the 96 hour test period. This pathogen was selected as representative of a worst case skin contaminant and a prevalent nosocomial infective organism. Each of the four inoculations averaged 119 colony forming units (cfu) per device, with cumulative counts over the test period averaging 125 cfu. The inoculum levels reflect the *S. aureus* levels found on the human skin.

To simulate the clinical environment, bolus injections were administered through the valve port once every 4 hours for 96 hours. Injections were performed using a 5 ml Carpuject® Luer Lock sterile cartridge. Prior to each injection, the SmartSite valve port was swabbed with sterile 70% isopropyl alcohol using commonly accepted practices for aseptic decontamination. Infusate was recovered and analyzed for microbial

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed Under FOIA Request # 2015-8140, Released by CDRH on 11-23-2015

contamination at 24, 48, 60, 72, and 96 hours. Negative and decontamination controls were tested to validate the effectiveness of the test method.

Results

Time Interval	Number of contaminated samples testing positive for *S aureus*	Number of decontaminated control samples testing positive for *S aureus*
Initial	0/20	0/20
24h	0/20	0/20
48h	0/20	0/20
60h	0/20	0/20
72h	0/20	0/20
96h	0/20	0/20

Conclusion

The results of the study show that no contamination was detected in the infusate for the 96 hour test period. This outcome demonstrates that the SmartSite needleless system, under the challenge of a simulated clinical environment, was successfully decontaminated after repeated inoculations with *S. aureus*. Additionally, the study demonstrates the ability to resist bacterial contamination through the valve after repeated inoculations by maintaining a closed system when not activated. **Although the contamination and decontamination passed 96 hours of testing, it is recommended that all IV sets be changed every 24 hours or per hospital protocol.**

Recommendations

Use aseptic procedure and decontamination technique as follows:

- Hold the lower portion of the Y-site and do not touch the top of the valve.
- Decontaminate with sterile 70% isopropyl alcohol swabs prior to each valve port actuation.
- While holding the lower portion of the Y-site, swab the top of the valve port with a back and forth motion or in accordance with hospital protocol for effective decontamination.

References

1. B.P. Simmons, T.M. Hooton, E.S. Wong, and J.R. Allen, Center for Disease Control and Prevention,"Guidelines for Prevention of Intravascular Infections," 1982; available from National Technical Information Service, Springfield, Va. 22161, PB84-923403.

2. Center for Disease Control and Prevention, "Intravascular Device-Related Infection Prevention; Guideline Availability"; Notice. September 27, 1995; Vol 60, No. 187: 499978-500006.

3. ECRI, "Needlestick-Prevention Devices," Health Devices. 1994, Vol. 23, Nos 8-9: 316-325.

4. Rotter, M.L. "Alcohols for antisepsis of hands and skin" *Handbook of Disinfectants and Antiseptics*, (Joseph M. Ascenzi, ed.) Mercel Dekker, Inc. New York, N.Y. 1996, p. 199.

5. *USP Pharmacopoeia XXIII*. Rockville, Md. 1995, p. 1689.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16. Appendix G. Biocompatibility Data

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ICU Medical, Inc.

May 8, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

RE: CLAVE Needleless Connector, 510(k) submission statement certifying the biocompatibility of materials.

I certify that the materials used to manufacture the CLAVE Needleless Connector are exactly the same as in the devices that are currently marketed in interstate commerce. The conditions of use for these materials are comparable to those in devices that are currently being marketed in interstate commerce.

If you have any questions, please contact me at (714) 366-2183.

Regards,

Arlene Dutchik

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

951 Calle Amanecer - San Clemente, CA 92673 • (714) 366-2183 • (800) 824-7890 • Fax (714) 366-8368

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

17. Appendix H. 510(k) Summary of Safety and Effectiveness

The following section is included as required by
the Safe Medical Device Act (SMDA) of 1990.

Name: ICU Medical, Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K970855

Applicant Information:
Date Prepared: May 14, 199
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

Device Information:
Trade Name: Clave Connector
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set

Equivalent Device:
IVAC SmartSite™

Device Description:
The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to Intravascular administration set.

Intended Use:
As an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

Comparison To Predicate Device:

Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needleless injection port to access any vein, or artery.	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silicone Rubber Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ICU Medical Inc.
CLAVE CONNECTOR

Comparison To Predicate Device:

Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needleless injection port to access any vein, or artery.	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silicone Rubber Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

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Questions? Contact FOIA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

18. Appendix I. Predicate Device Labeling

IVAC MEDICAL SYSTEMS™ MODEL 2000E

LUER LOCK SMARTSITE™ NEEDLELESS VALVE

APPROXIMATE PRIMING VOLUME = 0.1 ml
U.S.A. AND FOREIGN PATENTS PENDING.

DIRECTIONS-USE ASEPTIC TECHNIQUE

DO NOT INSERT NEEDLES DIRECTLY INTO VALVE PORT.

INSPECT SET. DISCARD SET IF END CAP IS MISSING OR LOOSE IN PACKAGE.
NOTE: THE VALVE PORT IS TWO-WAY AND LUER-LOCKING. SWAB SEPTUM WITH PREFERRED ANTISEPTIC PRIOR TO ACCESSING VALVE PORT.

PREPARE VALVE PORT:
1. REMOVE PROTECTIVE CAP ON MALE LUER LOCK.
2. CONNECT MALE LUER TO FEMALE LUER OF CONNECTING DEVICE.

PRIME VALVE PORT:
3. EXPEL ALL AIR AS NEEDED.
4. ATTACH ADMINISTRATION SET OR SYRINGE TO VALVE PORT.

FOR EMERGENCY ACCESS TO VALVE PORT REQUIRING THE USE OF A NEEDLE:
- ATTACH "PRN" ADAPTER TO VALVE PORT.
- USE AS STANDARD INJECTION SITE.
- DO NOT ALLOW NEEDLE TO TOUCH VALVE.

WARNINGS:
1. DO NOT INSERT NEEDLES DIRECTLY INTO VALVE PORT.
2. FOR UNATTENDED MEDICATION DELIVERY USE ONLY LUER-LOCKING SECONDARY SETS AND SYRINGES.
3. CONTRAINDICATED FOR MOST BLUNT CANNULA SYSTEMS.

NOTES:
1. FLUSH VALVE PORT IN ACCORDANCE WITH HOSPITAL POLICY AFTER OR BETWEEN:
- SMALL VOLUME INJECTIONS
- LIPID, BLOOD, OR BLOOD PRODUCT INFUSIONS
- BLOOD WITHDRAWALS
- INCOMPATIBLE MEDICATIONS
2. VALVE PORT DOES NOT CONTAIN DEHP-PLASTICIZED PVC IN THE FLUID PATH.
3. VALVE PORT DOES NOT CONTAIN LATEX RUBBER.

REPLACE EVERY 24 HOURS OR IN ACCORDANCE WITH CURRENT, RECOGNIZED GUIDELINES OF IV THERAPY. APPROPRIATE IV INFECTION CONTROL SHOULD BE OBSERVED.

652556

45 J

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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19. Appendix J. Predicate Device Promotional Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Cost Effectiv

ease of use

Smart Site™

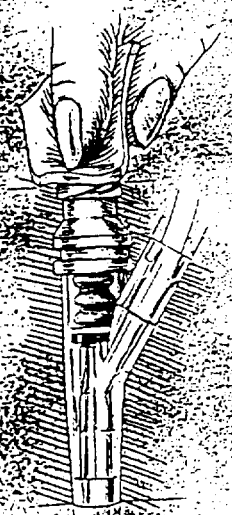
The smart needleless choice.

LATEX FREE

Compliance

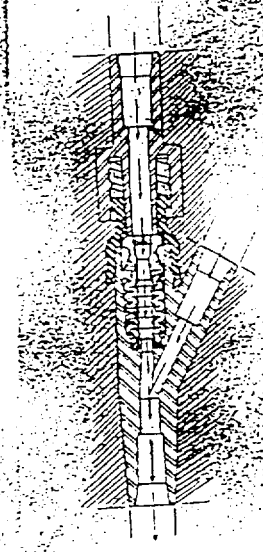
Its EASE OF USE and capless design represent a whole new level of convenience. Its needleless and **Latex Free** assembly mean a whole new level of safety. Introducing IVAC's **SmartSite**™ needleless system. Designed not only to reduce needleless system costs, but to help increase needleless COMPLIANCE, too. SmartSite. The smart **needleless** choice.

IT'S EASIER.



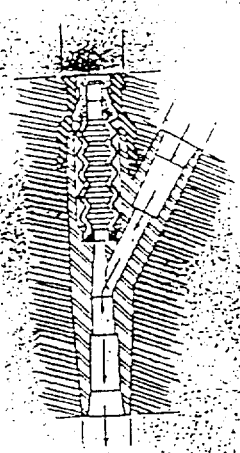
Swab.

IT'S FASTER.



Attach.

IT'S SMARTER.

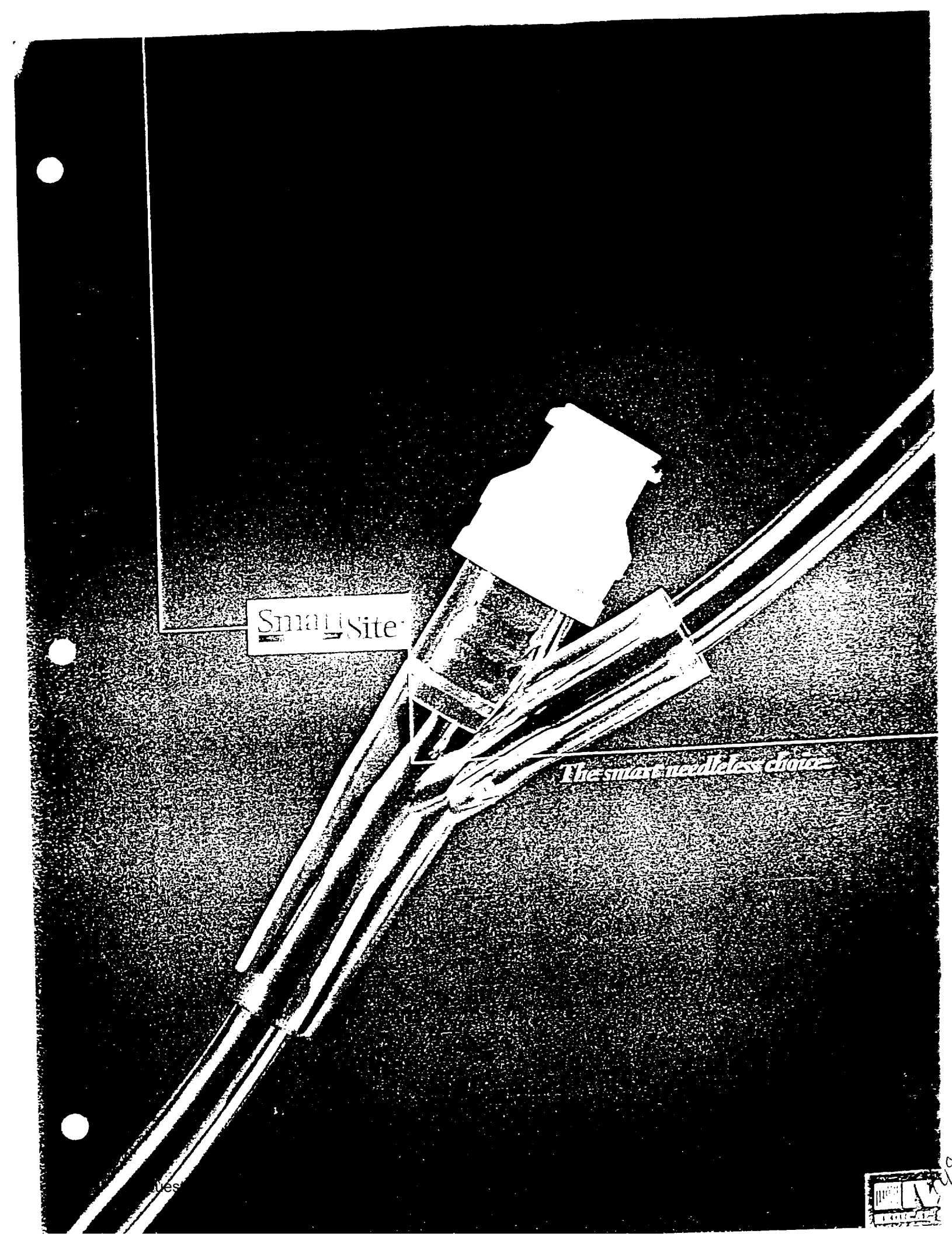


Detach.

IVAC MEDICAL SYSTEMS™

Corporate Office
10221 Wateridge Circle
San Diego, Ca 92121-1579
1-800-482-IVAC
http://www.ivac.com/-ivac

Questions? Contact


SmartSite
The smart needleless choice

Cost

NEEDLELESS AND CAPLESS, THE SMARTSITE SYSTEM HELPS PROTECT BOTH PATIENTS AND CARE GIVERS. AND, BY HELPING TO INCREASE COMPLIANCE WITH NEEDLELESS POLICIES, IT HELPS TO PROTECT YOUR FACILITY, AS WELL.

SMARTSITE CAN HELP YOU SAVE MONEY. THERE ARE FEWER PIECES TO INVENTOR AND NO CAPS OR CANNULAS TO BUY, REDUCING YOUR NEEDLELESS SYSTEM COSTS BY UP TO 30 PERCENT.

Ease of Use

WHY IS THE SMARTSITE SYSTEM EASIER TO USE THAN OTHER NEEDLELESS PRODUCTS? BECAUSE IT'S AN INTEGRATED IV SYSTEM. ONE THAT REQUIRES NO NEEDLES, NO CAPS AND NO EXTRA PIECES. YOU CAN SAVE ON TRAINING TIME, TOO. AND SINCE USING THE SMARTSITE SYSTEM IS AS SIMPLE AS SWAB-ATTACH-DETACH, IT CAN HELP INCREASE YOUR NEEDLELESS COMPLIANCE. SIMPLY STATED, IT COULDN'T BE SIMPLER.

LATEX FREE

CONCERNS ABOUT LATEX INTOLERANCE ARE ON THE RISE. WHICH IS WHY WE'VE ELIMINATED EVERY TRACE OF LATEX FROM THE SMARTSITE SYSTEM. BECAUSE WHAT'S GOOD FOR PATIENTS AND CARE GIVERS, IS GOOD FOR YOUR FACILITY, AS WELL.

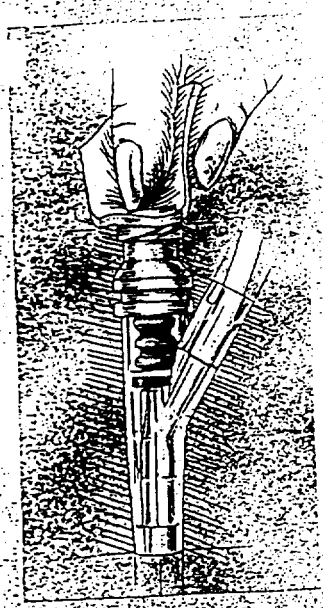
Needleless Intelligence.

Effective

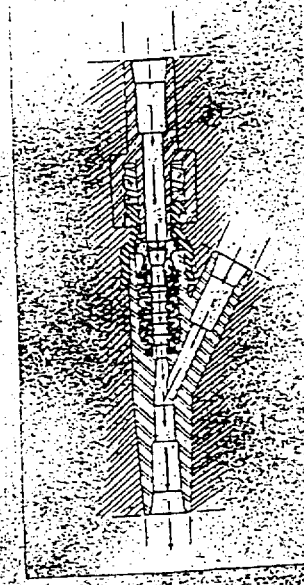
We've disposed of needles, we've eliminated caps, we've done away with latex. Introducing IVAC's SmartSite™ needleless system. Think of it as a whole new level in safety and convenience. One that not only saves you time and money, but helps increase needleless compliance, too.

SmartSite. The smart needleless choice.

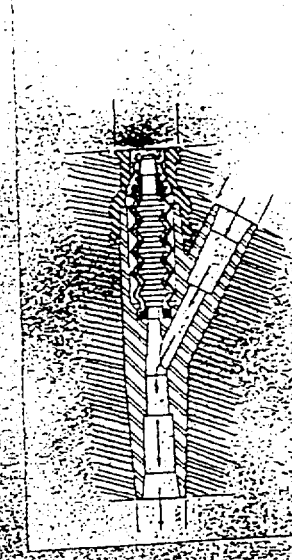
IT'S EASIER:



IT'S FASTER:



IT'S SMARTER:



Swab.Attach.Detach

[illegible] BY REDUCING THE NEED FOR NEEDLES, THE [illegible]

EASIER, FASTER AND SMARTER IS SAFER. YOU ALREADY ARE BY REDUCING THE NEED FOR NEEDLES. THE [illegible]

[illegible] ALSO HELPS REDUCE THE CHANCE OF NEEDLESTICKS AND WITH NO CAPS, EXTRA PARTS OR LATEX TO [illegible]

THE SMARTSITE SYSTEM MAKES LIFE EASIER AND SAFER FOR CARE GIVERS AND HELPS YOU SAVE TIME AND MONEY.

[illegible] IVAC

TOO. TO LEARN MORE, CONTACT YOUR LOCAL ACCOUNT CONSULTANT. [illegible]

SmartSite™

IVAC MEDICAL SYSTEMS

Corporate Office
10221 Wateridge Circle
San Diego, Ca 92121-1579
1-800-482-IVAC
http://www.ivac.com/~ivac

ISO 9001
Quality System
FM 31100

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 01, 1997

ICU MEDICAL, INC.
951 CALLE AMANECER
SAN CLEMENTE, CA 92673
ATTN: ARLENE DUTCHIK

510(k) Number: K970855
Product: CLAVE CONNECTOR

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Irene Naveau

Subject: 510(k) Number K970855

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept). Telephone Hold
- ☒ Accepted for review 3/24/97
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☒NO
Is this device subject to the Tracking Regulation?	☐YES	☒NO
Was clinical data necessary to support the review of this 510(k)?	☐YES	☒NO
Is this a prescription device?	☒YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☒NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒A 510(k) summary OR ☐A 510(k) statement

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

80/FPA/II/880.5440

Review: Patricia Cucanto (Branch Chief) OHDB (Branch Code) 4-30/97 (Date)

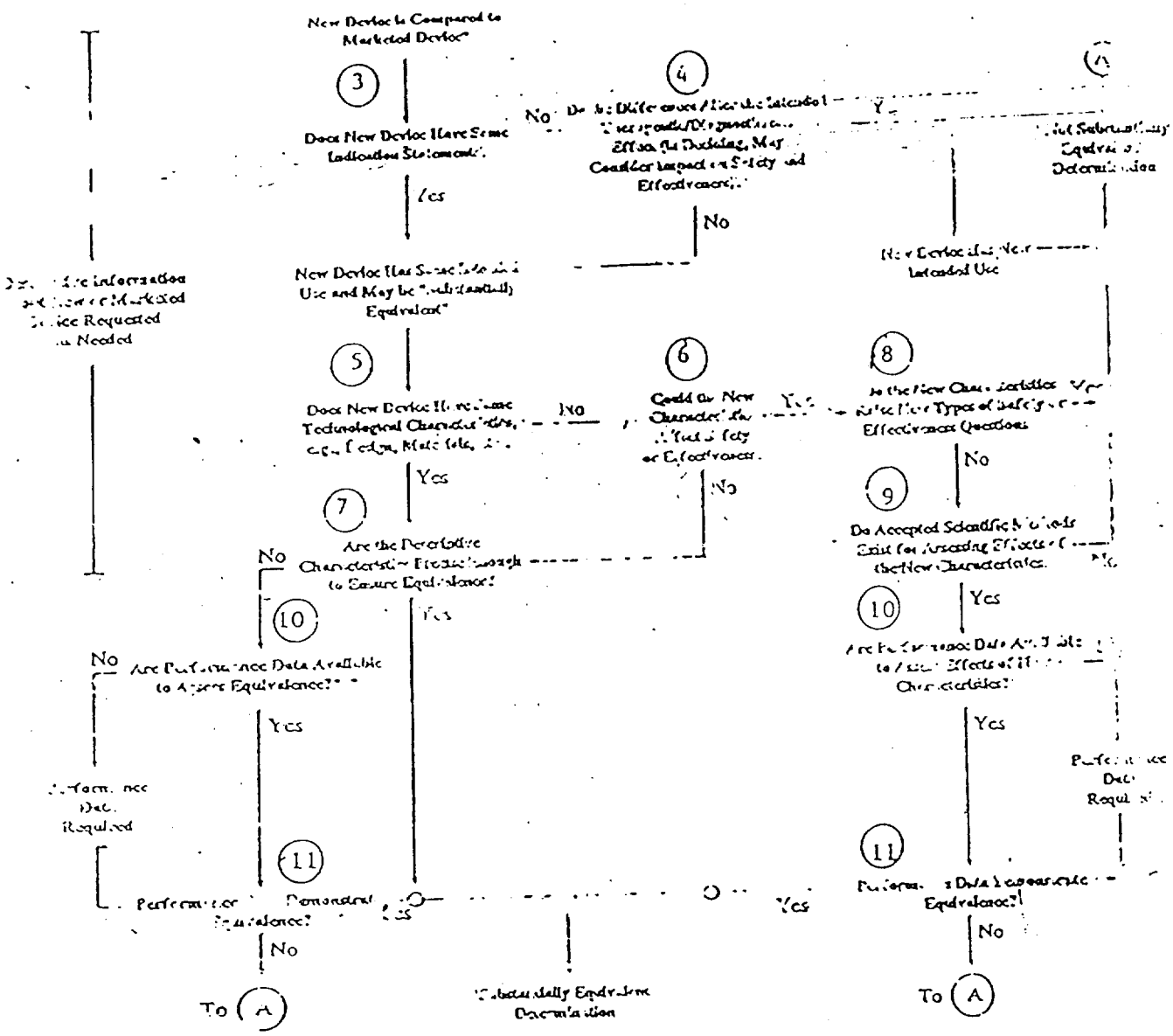
Final Review: _____ (Division Director) (Date)

Revised:11-20-96

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

DATE: April 29, 1997

HFZ-480

Irene Naveau

DDIG/GHDB

Review Record

K970855, Clave Connector

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Irene Naveau, Nurse Consultant
DDIG/GHDB, HFZ-420

And: Ms. Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.
(714) 266-2183

On this date, I initiated a telephone conversation with Ms. Dutchik to inform her of decisions made related to this submission.

The Clave Connector is a needle free device that may be an accessory to an IV administration set, an integral component of an IV administration set, or a stand-alone device used as an heparin lock injection port. The Clave Connector, via the 510(k) process, was originally cleared under K915571, and since that time, has been a subject of other 510(k) submissions with identical intended uses, e.g., to provide a needlefree access to the vein of a patient.

The reason for this 510(k) submission was ICU Medical's intent to revise the existing intended use to include the administration of fluids to a patient through a cannula placed in the artery or abdomen, as well as in the vein of a patient.

Patricia Cricenti, acting branch chief of GHDB, Dr. Joy Reid, Viola Hibbard RN, Brenda Bolden, biologist, and I met to discuss the implication for this expanded intended use and decided that it would be appropriate to contact someone in DRAERD to ascertain if there would be any contraindications for the use of the Clave Connector with a catheter that would be inserted into the abdomen. Brenda Bolden and I discussed this situation with Don St. Pierre and Carolyn Neuland, both branch chiefs in DRAERD, and agreed that the use of this device with an abdominal catheter was very vague and additional information was required to determine if the connector could be utilized in this manner. Ms. Neuland also stated that if the device was to be used as an accessory to peritoneal dialysis therapy, a separate 510(k) should be submitted with that specific intended use. In our telephone conversation, Ms. Dutchik stated that all reference to the "abdomen" would be deleted from this submission and that a separate 510(k) would be submitted to DRAERD's attention.

Brenda and I also spoke with Ms. Tara Ryan of the Interventional Cardiology Group of DCRND. We asked Ms. Ryan if there were any contraindications for the use of the Clave Connector with a catheter inserted in a patient's artery, to

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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which she responded that there were no contraindications, but suggested that a leak pressure test to burst should be performed. We also questioned whether the pressure of arterial blood flow would have an affect upon the valve,. and Ms. Ryan suggested that the sponsor perform back pressure testing to exceed the normal systolic pressure of 120-150 mmHg. Worst case scenario would be 200-250 mmHg, or more.

Ms. Dutchik stated that she would respond to the following:

1. Delete all mention of the word "abdomen" from this 510(k) so that the intended use would read that the connector will facilitate..."administration of fluids to a patient through a cannula placed in the vein or artery.

2. Amend the labeling, intended use, indications for use, and 510(k) summary.

3. Amend the replacement statement in the labeling to state that the device will be replaced within 24 hours or per hospital policy.

4. Perform back pressure testing to exceed normal systolic pressure, as recommended above.

5. Perform leak pressure testing to burst pressure.

6. Provide chemical names, different formulations of the materials used for the device.

7. Provide a short description of the device and reference the 510(k) number for the original Clave Connector.

RECOMMENDATION: Place this document on telephone hold to allow the patient to prepare a revision of this submission with appropriate changes to the document.

Irene Naveau 4/30/97

Irene Naveau

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Checklist for Premarket Notifications [510(k)s]

Device Trade Name: Clave Connector	K# 970855
Submitter Name: Ivac Medical, Inc.	
Date Received: 3/13/97 90 Day Due Date: 6/8/97	
Review Tier : 1 (2) 3	

Question	Yes	No
A. Is the product a device?	✓	
B. Is the device exempt from 510(k)?		✓
C. Expedited Review Status: Requested by sponsor,		✓
or identified by PILOT Division		
Granted by Pilot Division?		
D. Has this device been the subject of a previous NSE decision?		✓
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		✓
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Decision: ACCEPT ✓ REFUSE TO ACCEPT _____

Administrative Reviewer Signature: L. Pan Date: MAR 17

Supervisory Signature: Irene Nadeau Date: 3/24/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: Clave Connector K970855

Submitter Name: Ivac Medical, Inc.

General Content of a 510(k)	MISSING INFORMATION
1.* General Information: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, I) applicant's name and address. COMMENT:	
2.* Safe Medical Device Act of 1990 Requirements: a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement COMMENT:	
3.* Proposed Labeling: a) device and package labels, b) package insert, c) statement of intended use; d) promotional material that may accompany device. COMMENT:	
4.* Description of Device (or modification): diagrams, engineering drawings, or photographs. COMMENT:	

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5.*	Comparison Information: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness. COMMENT:	
6.	Biocompatibility Data: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use. COMMENT:	
7.	Sterilization Information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method. COMMENT:	
8.	Software Validation & Verification: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification. COMMENT:	
9.	Information Recommended in FDA Guidance: There is an FDA guidance document for this device that recommends additional data. COMMENT:	
10.	Kit Information: see attachment if this device is a kit. COMMENT:	

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Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 11, 1997

ICU MEDICAL, INC.
951 CALLE AMANECER
SAN CLEMENTE, CA 92673
ATTN: ARLENE DUTCHIK

510(k) Number: K970855
Received: 10-MAR-97
Product: CLAVE CONNECTOR

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.h or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K970855
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MAR 10 10 55 AM '97

March 6, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Attention: Document Control Clerk

RE: Revise Intended Use for Clave Connector

In compliance with the provision of Section 510(k) of the Act, ICU Medical, Inc. hereby notifies the Food and Drug Administration of the revised intended use of the Clave Connector manufactured by ICU Medical, Inc. in San Clemente, California.

The Clave Needleless Connector is considered by ICU Medical to be substantially equivalent to other products in commercial distribution.

This letter and the accompanying documentation constitute complete pre-market notification submission required under 510(k) of the Act.

We consider our intent to market this device as confidential information and request that it be considered as such by the FDA.

Regards,

Arlene Dutchik

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

HO

951 Calle Amanecer - San Clemente, CA 92673 • (714) 366-2183 • (800) 824-7890 • Fax (714) 366-8368

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ICU Medical

510(k) Notification

Clave Connector

Trade Name:	Clave
Manufacturer:	ICU Medical Inc. 951 Calle Amanecer San Clemente, CA, 92673
Registration Number:	2025816
Classification Name:	IV Administration Set, (80 FMG)
Regulatory Class:	Clave II

Submitted By:	ICU Medical Inc. 951 Calle Amanecer San Clemente, CA, 92673
Contact Person:	Arlene Dutchik
Contact Phone:	714-366-2183
Contact Fax:	714-366-8368

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ICU Medical Inc.
CLAVE CONNECTOR

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

1. GENERAL INFORMATION

1.1. Applicant

Date: March 6, 1997
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714) 366-2183

Signature: Arlene Dutchik

1.2. Trade Name
Clave Connector

1.3. Common Name or Classification Name
Intravascular Administration Set

1.4. Establishment Registration Number
025816

1.5. Facility Address

Manufacturer Address
ICU Medical Inc.
951 Calle Amanecer
San Clemente, CA 92673

Contract Sterilizer Address
Isomedics
43425 Business Park Dr.
Temecula, CA 92590
Registration Number: 2030624

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.6. Section 513 Device Classification

1.6.1. Classification
Devices of this type have been classified as Class II medical device per 21 CFR 880.5440, Intravascular Administration Set (80FMG).

1.7. Reason for Premarket Notification
Revise the intended use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein, artery or abdomen

1.8. Predicate Device Description

1.8.1. Name
IVAC Needle Free Valve Administration Sets (SmartSite™)

1.8.2. Predicate Device Company
IVAC, Inc.

1.8.3. Predicate Device 510(k)#
K960280

1.9. Special Controls/Performance Standard Compliance
ICU Medical Inc. knows of no published standard(s) pursuant to the requirements of Section 514 of the Act that are applicable to this product.

2. STATEMENT OF INTENDED USE

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein, artery or abdomen.

3. DEVICE LABELING

3.1. Device Labels
Carton Label (see Appendix A)
Primary Package Label (see Appendix A)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.2. Labeling
Instructions for use are printed on the Primary Package (see Appendix B).

3.3. Advertising
Promotional Material (see Appendix D).

4. SUBSTANTIAL EQUIVALENCE INFORMATION

4.1. Equivalent Device Information

Name: IVAC Needle Free Valve Administration Sets (SmartSite™)
Status: Currently in commercial distribution
510(k) #: K960280

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4.2. Comparative Information

Characteristic Compared	CLAVE® NEEDLELESS CONNECTOR	IVAC NEEDLE FREE VALVE ADMINISTRATION SETS (SMARTSITE™)
Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needleless injection port to access any intravenous, arterial or peritoneal line	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silastic Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

ICU Medical Inc.
CLAVE CONNECTOR

4.3. Comparative Performance Testing

PERFORMANCE CHARACTERISTIC	CLAVE® NEEDLELESS CONNECTOR (Avg. / Std)	IVAC NEEDLE FREE VALVE ADMINISTRATION SETS (SMARTSITE™) (Avg. / Std)
Fluid Flow (ml/min.)	176.6 / 17.8	114.5 / 22.0
Luer Retention (lbf)	11.7 / 1.7	11.5 / 3.0
Leak Pressure (psig)	23.5 / 1.1	57.4 / 17.3
Lipid Reactivity	No cracking after 72 hours	No cracking after 72 hours

4.4. Comparative Information

Sample Size Justification: sample sizes were selected to provide sufficient data points for calculation statistical parameters.

Sample size of n=60 for the ICU device was selected to provide sufficient data points to define a distribution of performance values.

Sample size of n=12 for the SmartSite device was selected due to limited access of competitor device

Testing Methodologies:

1.

2. Luer Retention: samples were tested by inserting a male luer slip into the proximal end port of the test sample at 5.5 lbs. insertion force and 90° twist using push/pull force gage. Verify luer slip is retained in the test sample.

3.

4.

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4.5. Change or Modification Information

Revise the intended use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein, artery or abdomen.

5. PREDICATE DEVICE LABELING

5.1. Labels

Predicate device labeling and Directions for use is included in Appendix I.

5.2. Advertising and Promotional Materials

Predicate device advertisement and promotional material is included in Appendix J.

6. DEVICE SPECIFICATIONS

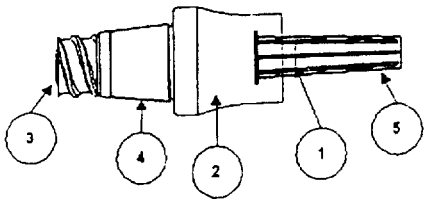
6.1. Description and Engineering Drawings

The Clave Connector is single use, sterile and non pyrogenic device intended for use as an accessory to Intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein, artery or abdomen.

The Clave Connector is provided sterile, in medical device grade components:

1. Internal Conduit
2. Housing
3. Silicone Seal
4. Ring
5. Breather Cap
6. Lubricant

(b)(4) [redacted]



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

[redacted]

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6.2. Voluntary Standards Conformance

There are currently no mandatory FDA Performance Standards for Intravascular Administration Sets.

7. MATERIAL/BIOCOMPATIBILITY INFORMATION

7.1.

Component Description	Material	Contact Category/Duration	Tripartite Evaluation
Internal Conduit	(b)(4) [redacted]	Blood Path Indirect/Prolonged	Pass
Housing		Blood Path Indirect/Prolonged	Pass
Silicone Seal		Blood Path Indirect/Prolonged	Pass
Lubricant		Blood Path Indirect/Prolonged	Pass
Breather Cap		Non-Contact Device	N/A
Ring		Non-Contact Device	N/A

8. STERILIZATION INFORMATION

The CLAVE Connector is provided sterile. The CLAVE Connector may be sterilized using radiation or ethylene oxide.

8.1. Sterilization Method

RADIATION
Radiation Dose: 2.5 to 4.0 megarads

8.1.1. Validation Method

The methods used to validate the sterilization cycle for the devices are based on the practices recommended by the Association of the Advancement of Medical Instrumentation (AAMI), Process Control Guidelines for Radiation Sterilization of Medical Devices (1991), Method 1. Pre sterilization Bioburden levels will be determined based upon Bioburden testing conducted on 10 samples for each of 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

Bioburden testing conducted on 10 samples for each of 3 different production lots. Bioburden testing will be conducted by a contract laboratory per established procedures. The mean and standard deviation of the CFU counts of the test samples will be reported. A Sub-process dosage shall be identified using Table 7 in the AAMI Process Control Guidelines for Radiation Sterilization of Medical Devices (1991), Method 1. The verification dose representing an SAL = 10^{-2} for the bioburden level shall be identified as the Sub-process dosage. A minimum of 100 samples shall be exposed to the Sub-process dosage(± 0.1 megarad or ± 10%, whichever is greater).

Successful completion of the verification dose exposure requires recovery of no more than two (2) positive cultures from a minimum of one hundred(100) products treated at that dose.

This validated dosage shall be audited 4 times per year to assure continued suitability.

8.2. Sterilization Method: ETHYLENE OXIDE

8.2.1. Validation Method

Devices will be sterilized ~~the~~ with ethylene oxide to achieve a sterility assurance level of 10^{-6}. The sterilization load must be validated to assure adequate aeration to achieve residual level of ≤ 25 ppm for EtO and EtCH: the residuals level for EtG will be ≤ 250 ppm. The sterilization cycle is validated in accordance with the requirements of ANSI/AAMI/ISO 11135, "Medical Devices, Validation and Routine control of Ethylene Oxide Sterilization. The half cycle approach consists of a total three (3) fractional half time exposures and (3) full time exposure runs. Cycle parameters are selected following a review of the product/packaging characteristics including complexity of the product resistance to permeation of the sterilant gas, permeation properties of the packaging, bioburden level, product density when palletized and the desired SAL (10^{-6}) to be achieved. Sublethal exposure runs utilizing graded population spore strips embedded into the documented reference product will be run. Fractional

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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positive/negative response will be used to document the comparative resistance of Biological Indicator (BI) challenge configurations and finished product. Comparative resistance data will be used to support the appropriateness of the BI system employed and to verify the sensitivity of the sterility test methods selected.

8.3. Sterility Assurance Level (SAL)

The device shall meet a Sterility Assurance Level (SAL) of 10^{-6} when sterilized using either sterilization method (radiation or ethylene oxide).

8.4. Sterile Packaging Description

The device uses a form-fill-seal thermoplastic pouch and waxed paper lidding material. The bottom material (StarTex C-Film) is a fiber-free clear film. The lidding material (Oliver 29HP-10) is a fiber-free, peelable paper lidding that provides a strong, breathable substrate.

8.5. Pyrogen Testing

Each product lot shall be tested using Limulus Amebocyte Lysate (LAL) Testing. Testing is performed by a contract laboratory following the guidelines set forth by the Food and Drug Administration in Guidelines on Validation of the Limulus Ameboytte Lusate Test as End Product Endotoxin Test of Human and Animal Parental Drugs, Biological Products and Medical Devices (1987).

This device is not intended for sterilization or reuse/re sterilization by the user.

9. SMDA INFORMATION

9.1. 510(k) Summary

A 510(k) Summary is included in the appendix H.

9.2. Truthful / Accurate Statement

A Truthful and Accurate Statement, as required by 21 CFR 807.87(j), is provided in the Appendix E.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10. Appendix A. Device/Packaging Labeling

Device Label

17 PEEL TO OPEN

CLAVE® Needleless Connector with Glow Ring

Catalog No. C1000G

Luer Lock Use Aseptic Technique

Sterile, Non-pyrogenic fluid path in unopened undamaged package.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

It is recommended that this device be changed per CDC Guidelines or per validated facility protocol.

See Directions for Use

Single Use Only. Do not resterilize.

PATENTS PENDING P1-3801M Rev A

ICU Medical, Inc.
951 Calle Amanecer
San Clemente, CA 92673
(800) 824-7890

Master Carton Label

ICU MEDICAL, INC.
(800) 824-7890
CATALOG NUMBER C1000G
CLAVE CONNECTOR WITH GLOW RING
STERILE - 100 UNITS
LOT NUMBER:
P/N R1-4962

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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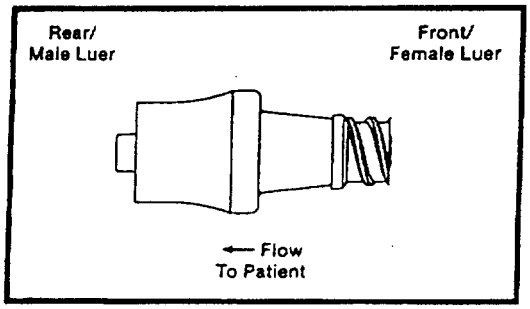
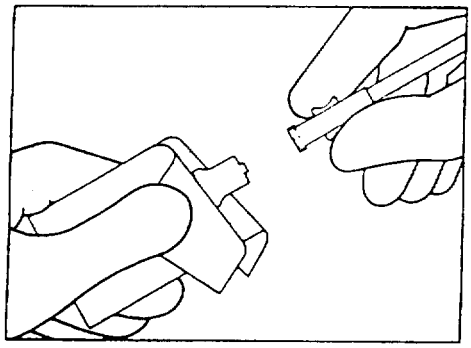
11. Appendix B. Directions for Use

Clave®® Needleless IV Connector
Catalog No. C1000 & C1000G

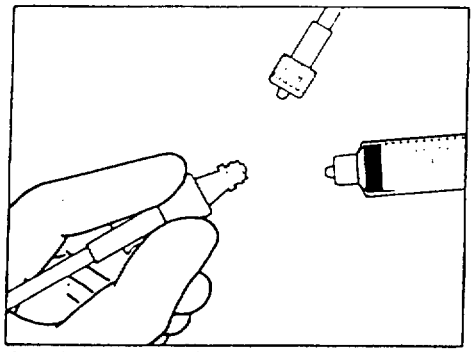


DIRECTIONS FOR USE

1. Peel open package at designated end and remove protective cap. Use Aseptic Technique.



2. Attach luer of catheter or extension set to rear of Clave®® Connector.
   Prime per facility protocol.
3. Swab silicone seal on top of Clave®® Connector per facility protocol. **Do Not Contaminate.**



4. Attach male end of IV tubing or syringe to Clave®® Connector. To secure - push and twist until tight. **Do Not Use Needles.**
5. To disconnect, twist IV connector or syringe until loose and pull apart. Do not remove Clave®® Connector from patient's catheter or tubing.
6. Flush Clave®® Connector after each use per facility protocol.
7. Clave®® Connector is closed. No capping is necessary.
8. To reconnect, repeat from step 3.

The Clave®® Connector is compatible with the following devices containing male luers. (As of Nov. 1995)

ADMINISTRATION AND PUMP SETS (All Standard bore sets)

Abbott Laboratories*	Baxter	IVAC
Churchill Medical Systems	Secure	IMED
McGaw, Inc.	Medex	MPS
Codan Medlon	Block	3M

*Except Energizer and Snap Dose sets

EXTENSION SETS (Standard bore and Minibore sets)

Abbott Laboratories	Baxter	3M
Summit Medical	McGaw, Inc.	IVAC
Churchill Medical Systems	Medex	IMED
Advanced Medical Devices		

Codan Medlon
- BC 591 Minibore, M/F LL, clamp, 7"

MPS
- EG-060-01 Minibore, M/F LL, clamp, 60"

EXTENSION SETS (Microbore sets)

Advanced Medical Devices Summit Medical

Baxter
- IM8516 Ultra-Microbore, M/F LL, filter, clamp, 60"
- IM8522 Ultra-Microbore, M/F LL, filter, clamp, 60"
- IM8521 Microbore, M/F LL, 36"
- IM8511 Ultra-Microbore, M/F LL, 60"
- IM6510 Ultra-Microbore, M/F LL, 36"

MPS
- EA-060-05 Ultra-Microbore, M/F LL, filter, 60"
- EA-060-01 Ultra-Microbore, M/F LL, clamp, 60"
- EA-036-01 Ultra-Microbore, M/F LL, 36"
- EB-060-01 Microbore, M/F LL, clamp, 60"

Churchill Medical Systems
- AMS-761 Microbore, M/F LL, clamp, 7"
- AMS-437 Microbore, M/F LL, clamp, 36"

SYRINGES/PREFILLED SYRINGES

Abbject	Monoject	Solopak
Terumo	Becton Dickinson (BD)	
Carpuject (with ICU Medical's CS-20)		

CAUTION: The Clave®® Connector is not compatible with every device containing male luers. DO NOT use any device containing a male luer with the Clave®® Connector unless it is on the above list or you have received written verification of its compatibility from ICU Medical. Please call (800) 824-7890 for verification.

Sterile, Non-Pyrogenic fluid path in unopened, undamaged package.

DO NOT USE NEEDLES
SINGLE USE ONLY - DO NOT RESTERILIZE

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. It is recommended that this device be changed per CDC Guidelines (24 to 48 hours) or per validated facility protocol.

ICU MEDICAL, INC.
951 Calle Amanecer
San Clemente, CA 92673
(714) 366-2183 (800) 824-7890
Patents Pending

R1-8848

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

12. Appendix C. Indications for Use

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein, artery or abdomen.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

13. Appendix D. Promotional Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CLAVE™ CONNECTOR

Simple safety that forces compliance...

ICU Medical, Inc.

One Piece, Swabable, Needleless IV connecting device that forces compliance with hospital's needle free policies.

Why go to the added expense of implementing a needleless system that permits the use of needles

With the Clave™ Connector, *Needleless means No Needles.*

FORCED COMPLIANCE...means no more needlesticks from IV connections.

Don't allow needlesticks to continue with your needleless connector.

No needle means no needlesticks.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

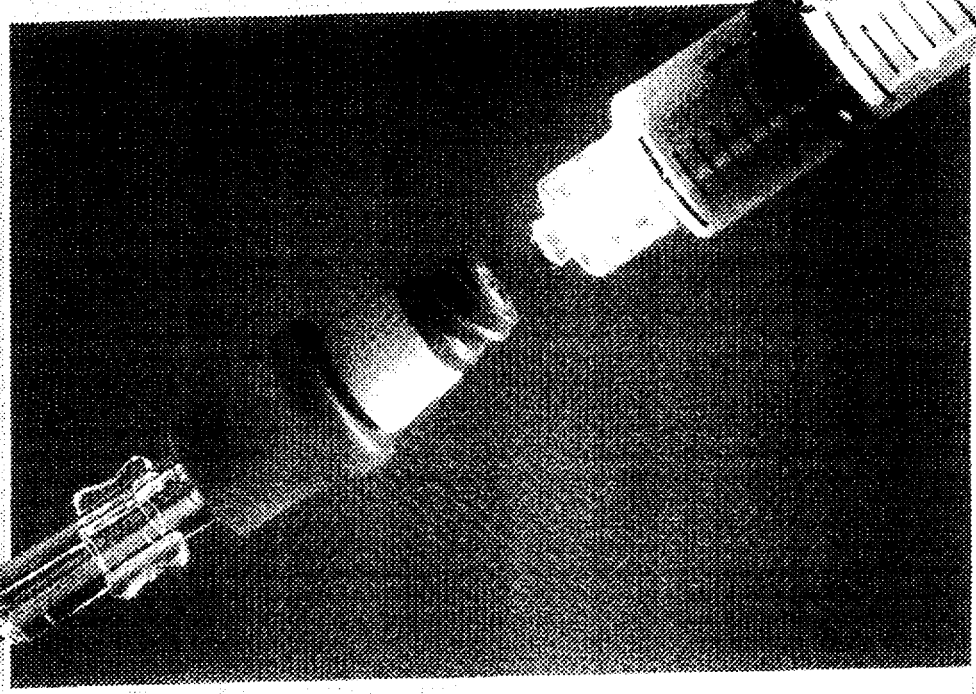
ICU Medical, Inc.

M1-1023

This document was released under FOIA request 2013-4111 (release initiated on 11/15/2013)

Clave® Connector

One Piece, Needleless Connector.
One Trip, to the bedside.
One Charge, to the patient.



SIMPLE SAFETY THAT FORCES COMPLIANCE.

The Clave® is the only one piece, swabable, needleless IV connector that will not permit needle access and does not require caps or cannulas.

•

WHY SPEND MONEY ON A NEEDLELESS SYSTEM THAT PERMITS THE USE OF NEEDLES?

Needleless should mean...No Needles. Engineered to eliminate IV related needles and needlesticks, the Clave® does not permit the use of needles thereby forcing compliance with current needle-free policies.

•

NEEDLELESS SHOULD MEAN...NO NEEDLESTICKS.

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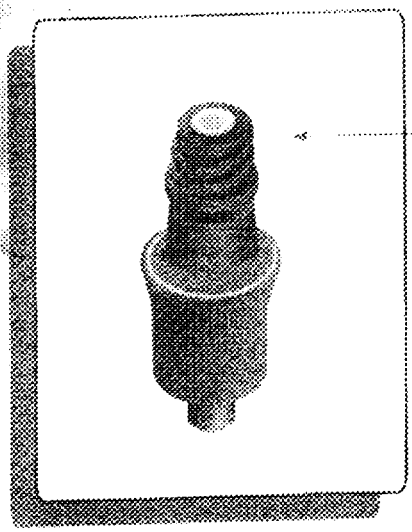
ICU
ICU Medical, Inc.
Toll Free (800) 824-7890
951 Calle Amanecer
San Clemente, CA 92673
(714) 366-2183

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

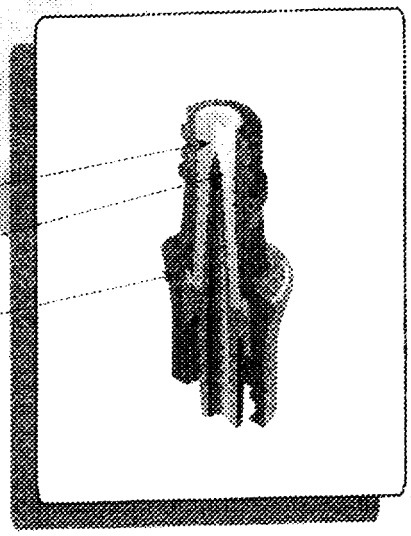
M1-1014

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

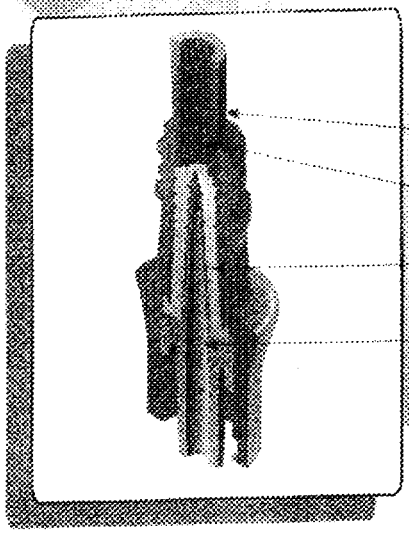
The CLAVE™ Connector



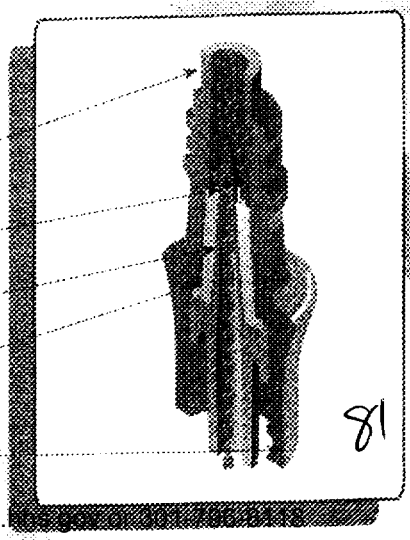
The Clave Connector



Compression Seal
Internal Piercing Element
Coupling Lock



Luer Tip
Fluid
Compression Seal
Internal Piercing Element



Luer Tip
Fluid Flow
Internal Piercing Element
Compression Seal
Coupling Lock

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14. Appendix E. Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as Regulatory Affairs Specialist of ICU MEDICAL, INC. I believe to the best of my knowledge, that all data and information submitted in the Premarket notification are truthful and accurate and that no material fact has been omitted.

Signed: Arlene Dutchik
Name: Arlene Dutchik
Position: Regulatory Affairs Specialist
Date: March 6, 1997

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

15. Appendix F. Microbial Challenge Study

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-8140; Released by CDRH on 11-23-2015

EXPERIMENTAL MICROBIAL CHALLENGE AND DECONTAMINATION OF CLAVE™ CONNECTORS

PAUL A. GIBILISCO, M.D., F.A.C.P., F.A.C.R.

GREGORY S. PAGE

Objective: To ascertain whether a closed system, needleless IV device, the Clave™ Connector, when microbiologically challenged, can be thereafter decontaminated with 70% Isopropyl Alcohol and maintain a sterile barrier.

Design: Experimental protocol simulating clinical practice.

Setting: Contract Quality Assurance GLP/GMP Microbiology Laboratory, Laboratory Services, Monrovia, CA.

Challenge Organism: Pseudomonas aeruginosa : in the first experiment, the nominal population of the inoculum utilized was 1.0 x 10^3/ml; and in the second experiment, the nominal population of the immersion pool was a 1.0 x 10^4/ml suspension. Note: Pseudomonas aeruginosa was chosen for its motility.

Results:

- *No positive cultures of Pseudomonas aeruginosa were observed following each of the 20 activations of the inoculated and thereafter decontaminated Clave™ Connectors.*
- *No positive cultures were observed in Clave™ Connectors after a continuous 72 hour engagement period, followed by an additional 19 activations and immersion into a 1.0 x 10^4 /ml nominal population suspension. Also, in the last phase of this experiment, no growth was observed in any of the test units after their void area was pressure filled from their male luer with sterile SCDB media.*

Conclusions:

- *Experimental contamination of the Clave™ Connector with Pseudomonas aeruginosa at its female luer was undertaken with repeated activations, and effective decontamination of the Clave™ Connector was achieved in 100% of the devices tested.*
- *After multiple and prolonged activations, the Clave™ Connector was able to maintain its sterile barrier when challenged by immersion into a 1.0 x 10^4 /ml nominal population suspension of Pseudomonas aeruginosa.*

Materials and Methods:

The following materials were used in this contamination study of the Clave™ Connector: Sterile test systems (Figures 1 and 2) including- Sterile Clave™ Connectors (ICU Medical, Inc., San Clemente, CA), sterile female to female luers, and sterile 10cc syringes (Becton Dickinson, East Rutherford, NJ); class 100 laminar flow hood, culture loops, sterile swabs, 58 x 138mm sterile screwcap jars, incubators (30-35° C and 20-25° C), a Vortex mixer, sterile 18 gauge needles, sterile gloves, alcohol wipes, sterile Pipets, 3000ml Aspirator bottles, sterile cleanroom garments, classroom 100 cleanroom, Bunson Burner, sterile Phosphate buffered water, water bath, Biological cabinet, and a centrifuge.

The following sterile Nutrient Media was used in this study: 1) Soybean Casein Digest Broth (SCDB), steam sterilized at 121° C, post sterilization pH 7.3 ± 0.2 @ 25° C, aseptically filled into sterile 10cc syringes, 2) Soybean Casein Digest Agar (SCDA), steam sterilized at 121° C, post sterilization pH 7.3 ± 0.2 25° C, poured into 150 x 15mm Petri dishes. The challenge microorganism used in this study was Pseudomonas aeruginosa, ATCC #15442 (Culti- loop®), titered to nominal populations of 1.0 x 10^4 spores/ml and 1.0 x 10^3 spores/ml.

Preparation

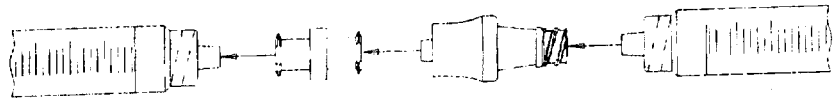
In a Class 100 LAF hood located within a class 100 cleanroom, 1920 individual syringes were aseptically filled with 10ml of the sterile SCDB from 3000ml aspirator bottles. The stainless steel luer adapters of the aspiration tubes were flame sterilized between each syringe fill. The syringes were incubated at 30-35° C for 72 hours and observed for signs of bacteri growth to verify the sterility of the units pric to use. A sterile 15ml tube of SCDB w preheated to 45° C in a waterbath, and a Cult Loop® package was opened in a biologic cabinet with the loop placed into preheat media until gelatin was rehydrated into t media. Four 1ml aliquots of suspension we transferred to separate 15 x 150mm SCDA Pet dishes and incubated for 24-48 hours. Aft incubation, the cells were harvested from 5 to isolates and placed into separate centrifuge tube each placed into a centrifuge and run at minimum of 1000 rpm for 15 minutes. Deb was aseptically removed using a sterile pipet and this process was repeated until all debris w removed. Serial dilutions were performed enumerate suspensions and test suspensions we prepared at nominal populations of 1.0 x 10^4 /r and 1.0 x 10^3 /ml. The final population suspensions was verified prior to use.

Decontamination Evaluation

The test articles were labeled follows: Clave™ Test group (20 ea.) = B1-B2 Clave™ Test group positive control (2 ea.) B21 & B22, Clave™ Test group negative contr (2 ea.) = B23 & B24, and Clave™ Populati verification samples (3 ea.) = PV1-PV3. T sterile test systems were removed and attached Clave™ Connectors; then the septum of ea Clave™ Connector was swabbed with separ swabs impregnated with a nominal populati 1.0 x 10^3 /ml suspension of Pseudomon aeruginosa, and allowed to dry at roo temperature. Following standard hospi procedures, repeated use simulation was beg by decontaminating each Clave™ Connect using alcohol prep pads (saturated with 7 isopropyl alcohol), and fully engaging each u with separate 10 ml SCDB filled syringes. Ea contaminated port of entry was swabbed o one time with only one prep pad. Media w pushed through the connectors and collected the distal IV luer using separate sterile 1 syringes. Sterile female luer connectors w used to connect the male luer of each Clave Connector to these sterile syringes. The syrin were capped and labeled, and incubated at 30-3 C for seven days. The test units w decontaminated and engaged for a total of replicate use simulations per unit, and cultu after each product engagement. The negat control samples were processed as test u omitting the challenge organism s procedure. The positive control samples w processed as test units omitting standard hospi decontamination procedures. Follow incubation, all test cultures were observed visible turbidity and results were recorded as (or (-) for bacterial growth. All positive gro was subcultured and presumptively identified confirm the presence of challe microorganism. Population verification performed on units identified as PV1 - PV3.

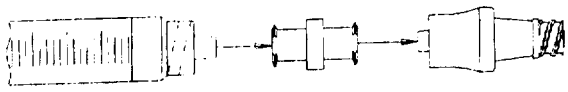
Sterile Test System

Figure 1



Distal Collection Syringe | Double Female Luer Adapter | Clave™ Connector | Prefilled Media Syringe

Figure 2



Prefilled Media Syringe | Double Female Luer Adapter | Clave™ Connector

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table I

	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12	B13	B14	B15	B16	B17	B18	B19	B20	Positive Controls B21	Positive Controls B22	Negative Controls B23	Negative Controls B24
1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
5	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
9	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
10	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
14	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
15	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
17	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
18	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
20	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	0/20	20/20	20/20	0/20	0/20

Microbial Challenge

The test articles were labeled as follows: Clave™ Connectors (20 ea.) - D1-D20 group, Clave™ Connector positive controls (2 ea.) -D21 & D22 group, and Clave™ Connector negative controls (2 ea.) -D23 & D24 group. Sterile test systems were attached to Clave™ Connectors. The Clave™ Connectors were decontaminated and engaged with 10cc SCDB filled syringes, and the test systems were primed. The syringes remained connected to the Clave™ for 72 hours. Following the initial 72 hour engagement period, the syringes were removed after flushing, and the media was collected at the distal Luer using a separate sterile 10cc syringe. Nineteen additional short term engagements were performed, each preceded by decontamination procedures, and systems were flushed with each engagement. Following the 20 decontamination/engagements of each unit, the Clave™ units were immersed for 90 seconds in a nominal 1.0 x 10^4 /ml culture of Pseudomonas aeruginosa , and allowed to dry at room temperature. The test systems were then decontaminated and incubated for 24 hours at 30-35° C. Following incubation, media inside the systems was aseptically transferred to separate 100ml SCDB jars and incubated for an additional 7 days at 30-35° C. A separate SCDB filled syringe was aseptically connected to each test system (see Figure 2). The Clave™ was pressurized from the distal SCDB filled syringe with sufficient pressure to fill the void between the silicone boot and spike conduit with media. The syringe barrel was immobilized using a flame sterilized 18 gauge x 2 1/2 hypodermic needle as a cotter pin. The system was incubated with SCDB filled void for 7 days at 30-35°C. The negative controls were processed as test samples, omitting immersion in challenge microorganism. The positive controls were processed as test samples after the reseal was enlarged with 18 gauge needles and observations of droplet formations due to exerted pressure were noted on raw data sheets. Following incubation, results were recorded as (+) or (-) and all bacterial growth was presumptively identified to confirm the presence of challenge microorganism.

Results:

In the first experiment (Table I), all positive controls were culture positive within 72 hours of incubation. All test units of Clave™ Connectors were culture negative after 7 days of incubation including the negative controls. The 20 inoculated and decontaminated Clave™ Connectors were cultured after each subsequent activation (up to 20 activations) and no Pseudomonas aeruginosa growth was observed.

In the second experiment, Parts A and B, and all positive controls were culture positive within 72 hours of incubation, and all negative controls were culture negative after 7 days of incubation. In Part A (Table II), no positive culture of Pseudomonas aeruginosa was observed in any of the 20 Clave™ Connectors after a 72 hour engagement period, followed by 19 additional activations. In Part B (Table III), these 20 Clave™ Connectors were aseptically connected at the male luer via a sterile female to female connector to a separate sterile SCDB filled syringe (Figure 2). Sufficient pressure was exerted to fill the void between the silicone boot and spike conduit to ensure that the SCDB completely filled the void area. Enough pressure was exerted such that SCDB droplet formations were observed on 7 of the 20 Clave™ Connectors. Each syringe barrel was then immobilized. No Pseudomonas aeruginosa growth was observed in any of the SCDB cultures taken from the male end of each Clave™ Connector after a 7 day incubation period.

Conclusions:

These experiments were designed to test the integrity of a closed system, one-unit, needleless device, the Clave™ Connector, by challenging this device with Pseudomonas aeruginosa. In the first experiment, effective decontamination of the female luer was demonstrated when the inoculated Clave™ Connectors were swabbed with 70% isopropyl alcohol and no positive cultures were observed after repeated activations.

In the second experiment, 20 additional test systems of Clave™ Connectors were activated for a 72 hour period, followed by 19 additional activations. Then, the prefilled media syringes were removed and the Clave™ Connectors were immersed into a 1.0 x 10^4 /ml nominal population suspension of the Pseudomonas aeruginosa. No growth of Pseudomonas aeruginosa was observed in any of the Clave™ Connectors tested. This demonstrates that the Clave™ Connector is able to maintain its sterile barrier following prolonged and multiple activations. In Part B of this experiment, the same Clave™ Connectors were pressure filled with SCDB from their male luer end and incubated for 7 days. No growth of Pseudomonas aeruginosa was observed after this 7 day incubation period. This demonstrates that the Pseudomonas aeruginosa was not able to ingress into the void area between the silicone boot and the spike conduit.

These experiments reveal that the Clave™ Connector is an effective, one-unit, closed system, IV device that resists microbial growth at its female luer end. Effective decontamination of Clave™ Connectors was achieved in 100% of the devices tested and no Pseudomonas aeruginosa was isolated from any Clave™ Connector after its internal integrity was challenged for microbial growth.

Table II

Product #	Result	Product	Result
D1	(-)	D11	(-)
D2	(-)	D12	(-)
D3	(-)	D13	(-)
D4	(-)	D14	(-)
D5	(-)	D15	(-)
D6	(-)	D16	(-)
D7	(-)	D17	(-)
D8	(-)	D18	(-)
D9	(-)	D19	(-)
D10	(-)	D20	(-)
Pos.Control D21	(+)		
Pos.Control D22	(+)		
Neg.Control D23	(-)		
Neg.Control D24	(-)		
Total (+) test units / # units	0/20		

Table III

Product #	Result	Product	Result
D1	(-)	D11	(-)
D2	(-)	D12 *	(-)
D3 *	(-)	D13 *	(-)
D4	(-)	D14	(-)
D5	(-)	D15	(-)
D6 *	(-)	D16 *	(-)
D7 *	(-)	D17	(-)
D8	(-)	D18	(-)
D9	(-)	D19 *	(-)
D10	(-)	D20	(-)
Pos.Control D21	(+)		
Pos.Control D22	(+)		
Neg.Control D23	(-)		
Neg.Control D24	(-)		
Total (+) test units / # units	0/20		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processing Study for the IVAC SmartSite Needleless System, FOIA Request # 2015-8140, Released by CDRH on 11-23-2015

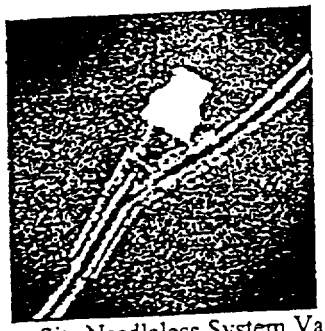
Contamination and Decontamination Study for the IVAC® SmartSite™ Needleless System

Wayne J. Rogers, Principal Investigator
Material Safety, Sterility Assurance and Environmental Affairs

Eleanor L. Fitzgerald, RN, BSN
Senior Clinical Study Specialist

Overview
A study was conducted to demonstrate the capability of the SmartSite capless valve to resist bacterial contamination through the valve after repeated inoculations with *Staphylococcus aureus*. The ability to effectively decontaminate the valve with 70% isopropyl alcohol was also tested.

As reported by the ECRI Health Devices publication on needlestick prevention, needleless devices are designed to reduce needlestick injuries and subsequent exposure to infected blood by decreasing the use of needles for IV administration. The SmartSite needleless system's unique valve design is intended to resist bacterial contamination through the valve by maintaining a closed system when not activated. The SmartSite needleless valve is activated with any standard luer lock or luer slip syringe, secondary IV set or other IV products. The valve opens when a luer end is inserted into the valve port and reseals when removed, thus preventing fluid flow after administration is complete.


SmartSite Needleless System Valve

Procedure
To validate the capability of this needleless valve to resist bacterial contamination of an IV administration set and to be effectively decontaminated, Silliker Laboratories of California, Inc., Carson, CA, conducted an independent in vitro laboratory study. As required by the United States Pharmacopoeia (USP) for sterility testing, a sample size of 20 SmartSite valves were tested. The valves were inoculated once every 24 hours with pathogenic *S. aureus* during the 96 hour test period. This pathogen was selected as representative of a worst case skin contaminant and a prevalent nosocomial infective organism. Each of the four inoculations averaged 119 colony forming units (cfu) per device, with cumulative counts over the test period averaging 125 cfu. The inoculum levels reflect the *S. aureus* levels found on the human skin.

To simulate the clinical environment, bolus injections were administered through the valve port once every 4 hours for 96 hours. Injections were performed using a 5 ml Carpuject® Luer Lock sterile cartridge. Prior to each injection, the SmartSite valve port was swabbed with sterile 70% isopropyl alcohol using commonly accepted practices for aseptic decontamination. Infusate was recovered and analyzed for microbial

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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contamination at 24, 48, 60, 72, and 96 hours. Negative and decontamination controls were tested to validate the effectiveness of the test method.

Results

Time Interval	Number of contaminated samples testing positive for *S aureus*	Number of decontaminated control samples testing positive for *S aureus*
Initial	0/20	0/20
24h	0/20	0/20
48h	0/20	0/20
60h	0/20	0/20
72h	0/20	0/20
96h	0/20	0/20

Conclusion

The results of the study show that no contamination was detected in the infusate for the 96 hour test period. This outcome demonstrates that the SmartSite needleless system, under the challenge of a simulated clinical environment, was successfully decontaminated after repeated inoculations with *S. aureus*. Additionally, the study demonstrates the ability to resist bacterial contamination through the valve after repeated inoculations by maintaining a closed system when not activated. **Although the contamination and decontamination passed 96 hours of testing, it is recommended that all IV sets be changed every 24 hours or per hospital protocol.**

Recommendations

Use aseptic procedure and decontamination technique as follows:

- Hold the lower portion of the Y-site and do not touch the top of the valve.
- Decontaminate with sterile 70% isopropyl alcohol swabs prior to each valve port actuation.
- While holding the lower portion of the Y-site, swab the top of the valve port with a back and forth motion or in accordance with hospital protocol for effective decontamination.

References

1. B.P. Simmons, T.M. Hooton, E.S. Wong, and J.R. Allen, Center for Disease Control and Prevention,"Guidelines for Prevention of Intravascular Infections," 1982; available from National Technical Information Service, Springfield, Va. 22161, PB84-923403.

2. Center for Disease Control and Prevention, "Intravascular Device-Related Infection Prevention; Guideline Availability"; Notice. September 27, 1995; Vol 60, No. 187: 499978-500006.

3. ECRI, "Needlestick-Prevention Devices," Health Devices. 1994, Vol. 23, Nos 8-9: 316-325.

4. Rotter, M.L. "Alcohols for antisepsis of hands and skin" *Handbook of Disinfectants and Antiseptics*, (Joseph M. Ascenzi, ed.) Mercel Dekker, Inc. New York, N.Y. 1996, p. 199.

5. *USP Pharmacopoeia XXIII*. Rockville, Md. 1995, p. 1689.

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16. Appendix G. Biocompatibility Data

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ICU Medical, Inc.

March 6, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

RE: CLAVE Needleless Connector, 510(k) submission statement certifying the biocompatibility of materials.

I certify that the materials used to manufacture the CLAVE Needleless Connector are exactly the same as in the devices that are currently marketed in interstate commerce. The conditions of use for these materials are comparable to those in devices that are currently being marketed in interstate commerce.

If you have any questions, please contact me at (714)366-2183.

Regards,

Arlene Dutchik

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

951 Calle Amanecer - San Clemente, CA 92673 • (714) 366-2183 • (800) 824-7890 • Fax (714) 366-8368

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17. Appendix H. 510(k) Summary of Safety and Effectiveness

The following section is included as required by
the Safe Medical Device Act (SMDA) of 1990.

Name: ICU Medical, Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant Information:
Date Prepared: March 6, 1997
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

Device Information:
Trade Name: Clave Connector
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set

Equivalent Device:
IVAC SmartSite™

Device Description:
The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to Intravascular administration set.

Intended Use:
As an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein, artery or abdomen.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comparison To Predicate Device:

Characteristic Compared	CLAVE® NEEDLELESS CONNECTOR	IVAC NEEDLE FREE VALVE IV ADMINISTRATION SETS (SMARTSITE™)
Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needleless injection port to access any intravenous, arterial or peritoneal line	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silastic Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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18. Appendix I. Predicate Device Labeling

IVAC MEDICAL SYSTEMS™ **MODEL 2000E**

LUER LOCK SMARTSITE™ NEEDLELESS VALVE

APPROXIMATE PRIMING VOLUME = 0.1 ml
U.S.A. AND FOREIGN PATENTS PENDING.

DIRECTIONS-USE ASEPTIC TECHNIQUE

DO NOT INSERT NEEDLES DIRECTLY INTO VALVE PORT.

INSPECT SET. DISCARD SET IF END CAP IS MISSING OR LOOSE IN PACKAGE.
NOTE: THE VALVE PORT IS TWO-WAY AND LUER-LOCKING. SWAB SEPTUM WITH PREFERRED ANTISEPTIC PRIOR TO ACCESSING VALVE PORT.

PREPARE VALVE PORT:
1. REMOVE PROTECTIVE CAP ON MALE LUER LOCK.
2. CONNECT MALE LUER TO FEMALE LUER OF CONNECTING DEVICE.

PRIME VALVE PORT:
3. EXPEL ALL AIR AS NEEDED.
4. ATTACH ADMINISTRATION SET OR SYRINGE TO VALVE PORT.

FOR EMERGENCY ACCESS TO VALVE PORT REQUIRING THE USE OF A NEEDLE:
- ATTACH PRN ADAPTER TO VALVE PORT.
- USE AS STANDARD INJECTION SITE.
- DO NOT ALLOW NEEDLE TO TOUCH VALVE.

WARNINGS:
1. DO NOT INSERT NEEDLES DIRECTLY INTO VALVE PORT.
2. FOR UNATTENDED MEDICATION DELIVERY USE ONLY LUER-LOCKING SECONDARY SETS AND SYRINGES.
3. CONTRAINDICATED FOR MOST BLUNT CANNULA SYSTEMS.

NOTES:
1. FLUSH VALVE PORT IN ACCORDANCE WITH HOSPITAL POLICY AFTER OR BETWEEN:
- SMALL VOLUME INJECTIONS
- LIPID, BLOOD, OR BLOOD PRODUCT INFUSIONS
- BLOOD WITHDRAWALS
- INCOMPATIBLE MEDICATIONS

2. VALVE PORT DOES NOT CONTAIN DEHP-PLASTICIZED PVC IN THE FLUID PATH.
3. VALVE PORT DOES NOT CONTAIN LATEX RUBBER.

REPLACE EVERY 24 HOURS OR IN ACCORDANCE WITH CURRENT, RECOGNIZED GUIDELINES OF IV THERAPY. APPROPRIATE IV INFECTION CONTROL SHOULD BE OBSERVED.

652556

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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19. Appendix J. Predicate Device Promotional Material

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Cost

NEEDLELESS AND CAPLESS, THE SMARTSITE SYSTEM HELPS PROTECT BOTH PATIENTS AND CARE GIVERS. AND, BY HELPING TO INCREASE COMPLIANCE WITH NEEDLELESS POLICIES, IT HELPS TO PROTECT YOUR FACILITY, AS WELL.

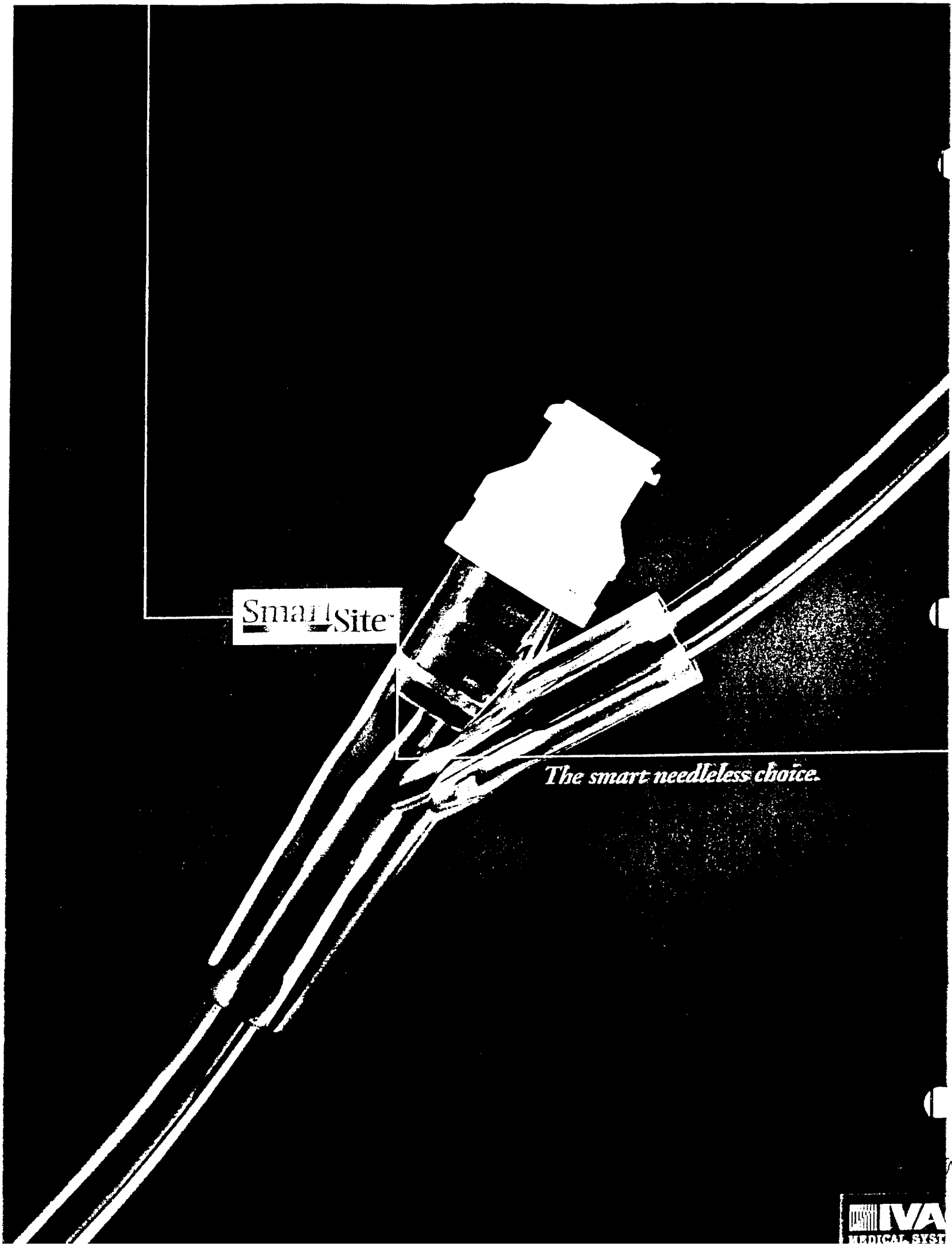
SMARTSITE CAN HELP YOU SAVE MONEY. THERE ARE FEWER PIECES TO INVENTORY AND NO CAPS OR CANNULAS TO BUY, REDUCING YOUR NEEDLELESS SYSTEM COSTS BY UP TO 30 PERCENT.

Ease of Use

WHY IS THE SMARTSITE SYSTEM EASIER TO USE THAN OTHER NEEDLELESS PRODUCTS? BECAUSE IT'S AN INTEGRATED IV SYSTEM. ONE THAT REQUIRES NO NEEDLES, NO CAPS AND NO EXTRA PIECES. YOU CAN SAVE ON TRAINING TIME, TOO. AND SINCE USING THE SMARTSITE SYSTEM IS AS SIMPLE AS SWAB-ATTACH-DETACH, IT CAN HELP INCREASE YOUR NEEDLELESS COMPLIANCE. SIMPLY STATED, IT COULDN'T BE SIMPLER.

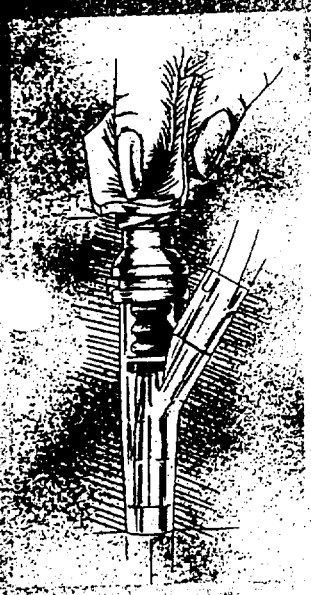
LATEX FREE

CONCERNS ABOUT LATEX INTOLERANCE ARE ON THE RISE. WHICH IS WHY WE'VE ELIMINATED EVERY TRACE OF LATEX FROM THE SMARTSITE SYSTEM. BECAUSE WHAT'S GOOD FOR PATIENTS AND CARE GIVERS, IS GOOD FOR YOUR FACILITY, AS WELL.


SmartSite
The smart needleless choice.
IVA
MEDICAL SYST

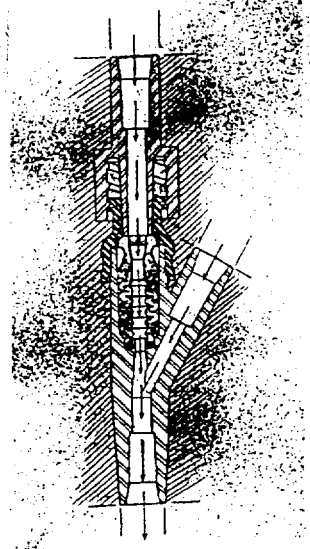
EASE OF USE and cupless design represent a whole new level of convenience. Its needleless and **Latex Free** assembly mean a whole new level of safety. Introducing IVAC's SmartSite™ needleless system. Designed not only to reduce needleless system costs, but to help increase needleless COMPLIANCE, too. SmartSite. The smart **needleless** choice.

IT'S EASIER:



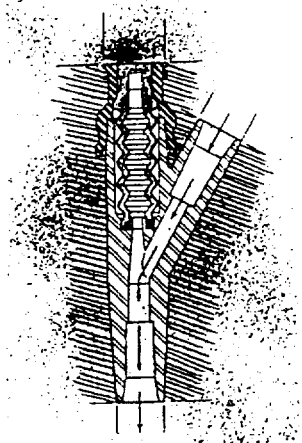
Swab.

IT'S FASTER:



Attach.

IT'S SMARTER:



Detach.

EASIER TO USE

SAVES ON LABOR

DOES THE SAFE THING

MONEY TOO TIGHT TO MENTION

IVAC DIRECT, INC.

IVAC MEDICAL SYSTEMS™

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ISO 9001 Quality System FM 31108

IVAC Corporate Office
10221 Wateridge Circle
San Diego, Ca 92121-1579
1-800-482-IVAC
http://www.ivac.com/-ivac

Contact BOAICB ... FORSTATUS@tda...

5/96

Cost Effectiv

of use

The smart needleless choice.

LATEX FREE

Compliance

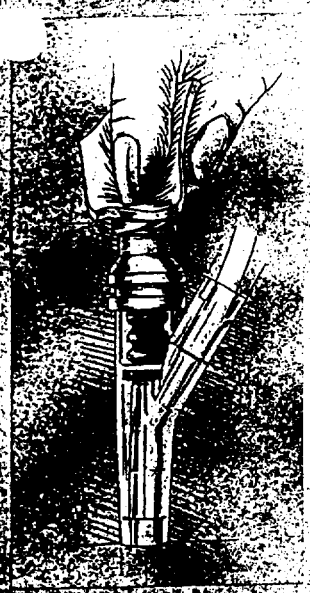
IVA
MEDICAL SYST

Effective

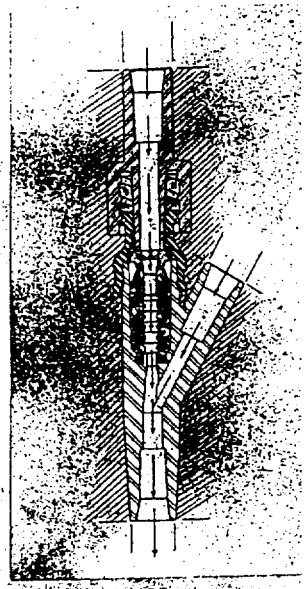
We've disposed of needles, we've eliminated caps, we've done away with latex. Introducing IVAC's SmartSite™ needleless system. Think of it as a whole new level in safety and convenience. One that not only saves you time and money, but helps increase needleless compliance, too.

SmartSite. The smart needleless choice.

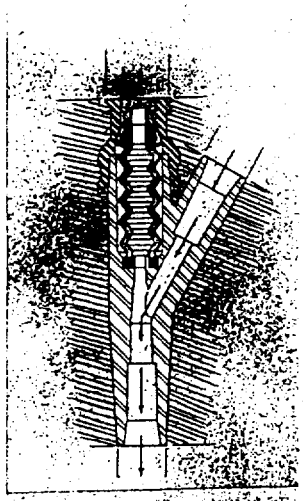
IT'S EASIER:



IT'S FASTER:



IT'S SMARTER:



Swab.Attach.Detach.

EASIER, FASTER AND [illegible] TOO. [illegible]

SYSTEM ALSO HELPS REDUCE THE [illegible] OF NEEDLESTICK [illegible] CAPS OR LATEX TO [illegible]

THE SMARTSITE SYSTEM MAKES LIFE EASIER AND SAFER FOR CARE GIVERS AND HELPS YOU SAVE TIME AND [illegible]

TOO. TO LEARN MORE, CONTACT YOUR LOCAL ACCOUNT CONSULTANT [illegible] IVAC

[illegible]US@[illegible]

SmartSite™

IVAC MEDICAL SYSTEMS

Corporate Office
10221 Wateridge Circle
San Diego, Ca 92121-1579
1-800-482-IVAC
http://www.ivac.com/~ivac

ISO 9001
Quality System
FM 31100

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K970855

17. Appendix H. 510(k) Summary of Safety and Effectiveness

The following section is included as required by
the Safe Medical Device Act (SMDA) of 1990.

Name: ICU Medical, Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K970855

Applicant Information:
Date Prepared: May 14, 199
Name: ICU Medical Inc.
Address: 951 Calle Amanecer
San Clemente, CA 92673

Contact Person: Arlene Dutchik
Phone Number: (714)366-2183
Fax Number: (714)366-8368

Device Information:
Trade Name: Clave Connector
Common Name: Intravascular Administration Set
Classification Name: Intravascular Administration Set

Equivalent Device:
IVAC SmartSite™

Device Description:
The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to Intravascular administration set.

Intended Use:
As an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comparison To Predicate Device:

Characteristic Compared	CLAVE NEEDLELESS CONNECTOR	[illegible]
Product Labeling	Sterile Use, Non-Pyrogenic, Sterile fluid pathway in unopened, undamaged package. Directions for use on labeling.	Sterile Use, Directions for use on labeling
Intended Use	Needleless injection port to access any vein, or artery.	Needleless valve (luer lock)
Design	One piece design activated by luer connection to allow fluid flow.	One piece design activated by luer connection to allow fluid flow.
Materials	Internal Conduit-Polycarbonate Housing-Polyester Silicone Seal-Silicone Rubber Ring-Polypropylene Lubericant-Flurosilicone Breather Cap-Polypropylene Packaging-Medical packaging grade fiber-free peelable paper lidding and pouching material.	Unknown

Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Arlene Dutchik
Regulatory Affairs Specialist
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

JUN 24 1997

Re: K970855
Trade Name: Clave Connector
Regulatory Class: II
Product Code: FPA
Dated: May 14, 1997
Received: May 19, 1997

Dear Ms. Dutchik:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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) 594-4618. 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 at (301) 443-6597.

Sincerely yours,

Patricia Cucinotti / for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12. Appendix C. Indications for Use

The ICU Needleless Connector is a single use, sterile, non-pyrogenic device intended for use as an accessory to intravascular administration set for the administration of fluids to a patient through a cannula placed in the vein or artery.

(Division Sign-Off) Patricia Cucuzza
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970855

Prescription Use ✓
(Per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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